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HEALTH TECHNOLOGY CASE STUDY 30

The Market for Wheelchairs

Innovations and Federal Policy

NOVEMBER 1984

Prepared by:

Donald S. Shepard, Ph.D.
Institute for Health Research, Harvard School of Public Health, Boston, MA; and
Health Services Research and Development Unit,
Veterans Administration Medical Center, West Roxbury, MA

and

Sarita L. Karon, M.S.
Institute for Health Research, Harvard School of Public Health, Boston, MA

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Preface

The Market for Wheelchairs: Innovations and Federal Policy is Case Study 30 in OTA's Health Technology Case Study Series. This case study has been prepared in connection with OTA's project on *Federal Policies and the Medical Devices Industry*, which was requested by the Senate Committee on Labor and Human Resources and endorsed by the Senate Committee on Veterans' Affairs. A listing of other case studies in the series is included at the end of this preface.

OTA case studies are designed to fulfill two functions. The primary purpose is to provide OTA with specific information that can be used in forming general conclusions regarding broader policy issues. The first 19 cases in the Health Technology Case Study Series, for example, were conducted in conjunction with OTA's overall project on *The Implications of Cost-Effectiveness Analysis of Medical Technology*. By examining the 19 cases as a group and looking for common problems or strengths in the techniques of cost-effectiveness or cost-benefit analysis, OTA was able to better analyze the potential contribution that those techniques might make to the management of medical technology and health care costs and quality.

The second function of the case studies is to provide useful information on the specific technologies covered. The design and the funding levels of most of the case studies are such that they should be read primarily in the context of the associated overall OTA projects. Nevertheless, in many instances, the case studies do represent extensive reviews of the literature on the efficacy, safety, and costs of the specific technologies and as such can stand on their own as a useful contribution to the field.

Case studies are prepared in some instances because they have been specifically requested by congressional committees and in others because they have been selected through an extensive review process involving OTA staff and consultations with the congressional staffs, advisory panel to the associated overall project, the Health Program Advisory Committee, and other experts in various fields. Selection criteria were developed to ensure that case studies provide the following:

- examples of types of technologies by function (preventive, diagnostic, therapeutic, and rehabilitative);
- examples of types of technologies by physical nature (drugs, devices, and procedures);
- examples of technologies in different stages of development and diffusion (new, emerging, and established);
- examples from different areas of medicine (e.g., general medical practice, pediatrics, radiology, and surgery);
- examples addressing medical problems that are important because of their high frequency or significant impacts (e.g., cost);
- examples of technologies with associated high costs either because of high volume (for low-cost technologies) or high individual costs;
- examples that could provide information material relating to the broader policy and methodological issues being examined in the particular overall project; and
- examples with sufficient scientific literature.

Case studies are either prepared by OTA staff, commissioned by OTA and performed under contract by experts (generally in academia), or written by OTA staff on the basis of contractors' papers.

OTA subjects each case study to an extensive review process. Initial drafts of cases are reviewed by OTA staff and by members of the advisory panel to the associated project. For commissioned cases, comments are provided to authors, along with OTA's suggestions for revisions. Subsequent drafts are sent by OTA to numerous experts for review and comment. Each case is seen by at least 30 reviewers, and sometimes by 80 or more outside reviewers. These individuals may be from relevant Government agencies, professional societies, consumer and public interest groups, medical practice, and academic medicine. Academicians such as economists, sociologists, decision analysts, biologists, and so forth, as appropriate, also review the cases.

Although cases are not statements of official OTA position, the review process is designed to satisfy OTA's concern with each case study's scientific quality and objectivity. During the various stages of the review and revision process, therefore, OTA encourages, and to the extent possible requires, authors to present balanced information and recognize divergent points of view.

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15	Elective Hysterectomy: Costs, Risks, and Benefits: Carol Korenbrot, Ann B. Flood, Michael Higgins, Noralou Roos, and John P. Bunker (OTA-BP-H-9(15))
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[b]Original publication numbers appear in parentheses.

[c]The first 17 cases in the series were 17 separately issued cases in *Background Paper #2: Case Studies of Medical Technologies*, prepared in conjunction with OTA's August 1980 report *The Implications of Cost-Effectiveness Analysis of Medical Technology*.

[d]Background Paper #3 to *The Implications of Cost-Effectiveness Analysis of Medical Technology*.

[e]Background Paper #5 to *The Implications of Cost-Effectiveness Analysis of Medical Technology*.

[f]Background Paper #1 to OTA's May 1982 report *Technology and Handicapped People*.

[g]Background Paper #2 to *Technology and Handicapped People*.

OTA Project Staff for Case Study #30

Roger Herdman[1] and H. David Banta,[2] *Assistant Director, OTA*
Health and Life Sciences Division

Clyde J. Behney, *Health Program Manager*

Jane E. Sisk, *Project Director*

Cynthia P. King,[3] *Analyst*

John C. Langenbrunner,[4] *Analyst*

Katherine E. Locke, *Research Assistant*

H. Christy Bergemann, *Editor*

Virginia Cwalina, *Administrative Assistant*

Rebecca I. Erickson, *Secretary/Word Processor Specialist*

Brenda Miller, *Word Processor/P.C. Specialist*

[1]Since December 1983
[2]Until August 1983
[3]Since December 1983
[4]Until November 1983

Advisory Panel for Federal Policies and the Medical Devices Industry

Richard R. Nelson, *Chair*
Institute for Social and Policy Studies, Yale University
New Haven, CT

William F. Ballhaus
International Numatics, Inc.
Beverly Hills, CA

Ruth Farrisey
Massachusetts General Hospital
Boston, MA

Peter Barton Hutt
Covington & Burling
Washington, DC

Alan R. Kahn
Consultant
Cincinnati, OH

Grace Kraft
Kidney Foundation of the Upper Midwest
Cannon Falls, MN

Joyce Lashof
School of Public Health
University of California
Berkeley, CA

Penn Lupovich
Group Health Association
Washington, DC

Victor McCoy
Paralyzed Veterans of America
Washington, DC

Robert M. Moliter
Medical Systems Division
General Electric Co.
Washington, DC

Louise B. Russell
The Brookings Institution
Washington, DC

Earl J. Saltzgiver
Foremost Contact Lens Service, Inc.
Salt Lake City, UT

Rosemary Stevens
Department of History and Sociology of Science
University of Pennsylvania
Philadelphia, PA

Allan R. Thieme
Amigo Sales, Inc.
Albuquerque, NM

Eric von Hippel
Sloan School
Massachusetts Institute of Technology
Cambridge, MA

Edwin C. Whitehead
Technicon Corp.
Tarrytown, NY

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OTA Note

These case studies are authored works commissioned by OTA. Each author is responsible for the conclusions of specific case studies. These cases are not statements of official OTA position. OTA does not make recommendations or endorse particular technologies. During the various stages of review and revision, therefore, OTA encouraged the authors to present balanced information and to recognize divergent points of view.

1.
Summary and Policy Issues

1. Summary and Policy Issues

SUMMARY

The Study

Wheelchairs, for many disabled persons, are essential medical devices for work, mobility, and recreation. The characteristics, prices, and durability of these chairs are critical both to the quality of life of their users and to the costs incurred by the users, insurers, and government agencies.

This case study focuses on how Federal Government policies affect innovations[1] in wheelchair characteristics. In this chapter, these findings are summarized. In subsequent chapters, wheelchairs and their market (ch. 2), the role of the Federal Government (ch. 3), and relevant economic theories of innovation (ch. 4) are described. Findings of a telephone survey of wheelchair manufacturers (ch. 5) are reported, and case studies of innovation based on a field visit (ch. 6) are presented.

The Device and Its Market

One American in 200 (approximately 1.2 million total in 1977) is a wheelchair user (36). Just under half the users in 1977 were nursing home residents, and this user population is expected to grow by an annual rate of 1.5 percent (25). In 1982, an estimated 338,000 wheelchairs of all types were sold in the United States, for total retail sales of $126 million. Wheelchairs fall into four categories: 1) general-purpose manual wheelchairs, 2) power (electric) wheelchairs, 3) sports wheelchairs, and 4) power alternatives (vehicles that function as wheelchairs, but often look more like golf carts than chairs). General-purpose manual chairs are, by far, the largest segment sold. Manual wheelchairs serving rental or institutional needs (transport within a health care institution) represent 250,000 of the total annual number of chairs sold.

Until 1978, the market was dominated by one manufacturer, Everest & Jennings, Inc. (E&J), which had 90 percent of U.S. sales. However, in that year, E&J settled an antitrust suit and relocated its plant. This situation slowed deliveries and weakened E&J's market position, offering other manufacturers the opportunity to strengthen their market shares. As a result, by 1983, there were approximately 53 manufacturers and importers of wheelchairs in the United States (37). Since 1978, E&J's sales have slightly declined in absolute terms, but much more in market share. In 1983, Invacare Corp., whose sales have risen rapidly, overtook E&J as the leader in number of industry sales, although E&J remained first in dollar value of wheelchair sales. (E&J projected its total 1983 sales, including non-wheelchair products, at $65 million.) The importance of these and a few other large firms suggests that the wheelchair market is oligopolistic.[2] Few details on market shares by type of wheelchair or manufacturer are available.

Purchase costs of a wheelchair vary from $200 to $3,000, depending on the type of wheelchair (manual, power, sports, or power alternative), the number of accessories and custom features, the quality of the construction and materials, and the manufacturer.

Maintenance and repair costs of wheelchairs are substantial. Over an average 3- to 4-year wheelchair lifetime, cumulative repair costs are sometimes more than initial purchase costs. The most frequently needed repairs are replacement of tires and upholstery. Maintenance and repair costs vary among models, however, and stainless steel chairs even come with a lifetime warranty on the frame. Comparison of costs of different wheelchair models is more meaningful if total annualized costs are computed. Total annualized costs

[1]For this report, an "innovation" is any product or product modification that substantially improves the quality or decreases the cost of a product, while introducing a technology, material, or concept not previously found in any similar product on the market (see ch. 4).

[2]In an oligopoly, a few suppliers dominate the market, and competition is limited by the knowledge that an action by one firm will prompt a reaction by the others.

of a wheelchair are the sum of: 1) the purchase price divided by a factor based on expected years of use, and 2) the annual repair and maintenance costs. For power chairs, this cost amounts to $1,600 per year, of which over half is maintenance and repairs (calculated in ch. 2).

The wheelchair market is dominated by third-party reimbursement. The influence of third-party reimbursement is direct for prescription wheelchairs and indirect for institutional and rental chairs. About half of all wheelchair purchases are at least partially funded by government and another 40 to 45 percent by private insurers. Only 5 to 10 percent are paid for totally by the user. The largest single purchaser of wheelchairs is the Veterans Administration (VA), which reportedly purchased 11 percent of wheelchairs in 1976 (17). The extensive amount of third-party reimbursement steers innovation to devices that can expect to receive such funds. The policies of the different insurers vary; and, although all of them will pay for a wheelchair that is "medically necessary," the meaning of this term varies. Some payers, such as the VA and Medicaid in Massachusetts, consider wheelchair alternatives, or accessories that provide psychological benefit to the user, to be medically necessary. Others, such as Medicare, will pay only for the most minimal type of equipment needed to provide mobility and to meet other physical needs of an individual patient. Wheelchair repairs are covered (or provided) in full to eligible users under the VA, Medicaid, and the health maintenance organization surveyed for this study. They are also covered by Medicare, subject to maximums, deductibles, and 20-percent coinsurance. However, the private insurer interviewed for this study, Blue Cross of Massachusetts, did not pay for repairs. Payers appear to consider only initial purchase costs, not lifetime costs, in deciding which wheelchair to supply.

The emphasis on price over performance in the reimbursement procedures for general manual wheelchairs has probably discouraged innovation. As manufacturers have difficulty selling a higher priced, higher quality, manual wheelchair, they probably have little reason to produce one.

Federal Policies

Wheelchair users are protected by the Rehabilitation Act of 1973, which generally prohibits discrimination on the basis of physical or mental handicap and requires that public buildings be accessible to handicapped people. Undoubtedly, the physical modifications of buildings and grounds, transportation systems, and many private accommodations and increased public concern have stimulated demand for wheelchairs.

Government research and development (R&D) efforts on wheelchairs appear modest in relation to the number of users. Available data show 1983 R&D expenditures specifically directed at wheelchairs to be $750,000 by the National Institute of Handicapped Research, $511,000 by the VA, and $50,000 by the National Aeronautics and Space Administration.

The Federal Government is a major purchaser of wheelchairs not only through the VA, but also through Medicaid (which probably spent nearly $32 million on wheelchairs nationally in 1982) and Medicare. Specific data on Medicare expenditures for wheelchairs are not available.

Wheelchairs themselves are covered under legislation concerning medical devices. The Food and Drug Administration (FDA) classifies[3] and regulates the marketing of medical devices, including wheelchairs. Only manual wheelchairs for short-term indoor use are in Class I. All other currently marketed wheelchairs fall into Class II, while the most risky chair, a curb-climber, falls into Class III. FDA is working on developing performance standards for wheelchairs in cooperation with

[3]There are three FDA regulatory classes of medical devices according to the potential risks they pose: Class I, general controls, encompasses devices for which general controls are sufficient to provide reasonable assurances of safety and effectiveness. Class II, performance standards, contains devices for which general controls are considered insufficient to assure safety and effectiveness, and information exists to establish performance standards. Class III, premarket approval, applies to devices for which Class I general controls are insufficient, information does not exist to establish a performance standard, *and* the device supports life, prevents health impairment, or presents a potentially unreasonable risk of illness or injury (35).

the Rehabilitation Engineering Society of North America. These standards are not expected to be completed for several more years, however.

FDA investigates claims for unsafe products that are brought directly to it. When a series of claims requires action, FDA usually attempts to have the manufacturer voluntarily correct the problem, if possible, and recall defective products.

The Federal and State judicial systems serve as judges of product liability. Manufacturers are generally liable for injuries caused by negligence in design or manufacture or, in many cases, inadequate performance of their products. Although most manufacturers subject their products to extensive testing, accidents still happen. Physicians, therapists, and dealers are also at risk for negligence or failing to inform users properly regarding risks of and alternatives for the products they prescribe or sell. As a result, users may be hesitant to try substantially new products. The fear of product liability suits causes manufacturers, physicians, therapists, and dealers to hesitate to make, fit, or sell products that are significantly different from those already established. These fears of liability retard the innovative process.

Manufacturer Survey

Eleven wheelchair manufacturers were surveyed by telephone interview regarding their innovations in the last decade, their R&D efforts, their marketing methods, and the effect of government policies on their operations. The researchers found that most innovations have been refinements of existing products, with an emphasis on usefulness to active users.

Most respondents called their R&D departments crucial to the success of their companies. The 15 innovations identified in the survey were reportedly developed with private R&D. The few manufacturers that provided quantitative data on their R&D effort gave a median of 4 percent of sales. If this share applied to the industry generally, it indicates a total annual private R&D effort of $5 million, several times larger than that of the Federal Government.

Other findings of the survey involved marketing, reimbursement, and legal issues. Dealers were the important target for marketing (mentioned by 82 percent of respondents), followed by institutions and users. Trade shows were the most commonly mentioned marketing tool. Marketing strategies aimed at the end users were most significant for innovative products of small companies. Reimbursement policies were important primarily to manufacturers of innovative products. Products that are fairly typical of their kind tend to be assured of third-party coverage. The high cost of an innovative product, lack of clear-cut product liability laws, and the vulnerability of the manufacturer to frequent and successful lawsuits were cited as major obstacles to innovation.

Case Studies of Innovations

The authors studied the Power Rolls® IV, made by Invacare Corp., as an example of a successful past innovation. This innovation was pushed from conception to market in approximately 2 years. The product resulted from market research that examined products that were currently available and needs that were not being met, as identified by the end users. However, reimbursement policies and product liability were also considerations and played limiting roles in the design and production of the product. Although the Power Rolls® IV offered several advantages over current products, it was designed to be competitively priced to broaden third-party reimbursement. It was extensively tested for safety and durability. A strong sales force successfully gained the interest of dealers. In the first 3 years that it has been available, the Power Rolls® IV has gained 25 percent of the U.S. market for powered wheelchairs.

The second innovation studied was a curb-climbing wheelchair available in parts of Europe, but not the United States. According to this study, five significant factors that limited innovation in this country were: product liability, R&D funding, reimbursement policies, user preference, and technology transfer between countries. Product liability, reimbursement policies, and import duties also discourage the import of this product.

POLICY ISSUES

Monitoring Durability and Computing Annualized Costs of Different Wheelchairs

When purchasers of wheelchairs face a choice among alternative models and manufacturers, they need to determine which choice provides the best value for the money. A model with a higher initial purchase price may save money later through lower repair costs. In order for government and other purchasers to evaluate different wheelchairs properly, systematic data are required on the length of useful life and maintenance costs of wheelchairs.

The VA and the National Institute of Handicapped Research might undertake such analysis. VA facilities and certain users could be identified as "monitoring sources" to maintain careful records of the timing, nature, and cost of repairs and the type of use for the chair. Costs could be summarized as annualized cost per year of use. This reporting would be analogous to the annual cost of electricity indicated on the label of a new refrigerator. VA therapists and statisticians could select the chairs to be evaluated and choose veterans to serve as a representative sample of users. Organizing this monitoring effort like a research study may be desirable. Participants must be informed of the benefits, responsibilities, and risks (none known) of participation.

Since wheelchairs differ in features and quality, the one with the lowest annualized cost is not necessarily the appropriate one. But third-party payers could demand some justification before reimbursing for costs considerably above the minimum for a similar product. If models of wheelchairs with the lowest annualized cost were reimbursed most easily and quickly, then the other manufacturers might be encouraged to increase quality so as to decrease maintenance and thus total annualized costs. If such effects occurred, both quality and cost-containment goals could be served. The VA, for example, could also consider basing its procurement program on similar annualized cost analyses, rather than only on purchase price and past impressions.

It may be argued that a reimbursement system that encourages high-quality products will also encourage costly products—a problem for a medical care system that is trying to limit spending. One way in which the reimbursement systems, especially Medicare, have attempted to limit their costs has been to base reimbursement rates on costs for previous, rather than current, years. If an innovation raises costs, the increase is not recouped for at least 2 years. Simply basing reimbursement rates on current prices could have a beneficial effect on innovation. If manufacturers knew that their products would be reimbursed at something close to their charge and that better performance could command a higher price, they might be encouraged to implement some of the innovative ideas they currently have. However, as more costly innovations would be introduced, the average price on which the reimbursement rate is based would rise and spending would increase.

A possible approach would be to borrow the concept of price indexes from payment systems for hospital care. Payment rates could be adjusted annually for changes in prices of inputs (labor and materials), complexity, and productivity. Manufacturers would then have the security of knowing that they could sell their products at a fair price. But such an approach would require that payers acquire additional technical expertise and would still entail continuing increases in prices and expenditures.

The problem remains of how to pay for higher quality products while encouraging manufacturers' efforts to maintain quality. One possibility would be to categorize products on the basis of quality, as determined through effectiveness analyses. Products that are more effective could be reimbursed at a higher rate, or at a greater percentage of the average cost of all wheelchairs. Manufacturers would then have to make a better product to receive a higher level of reimbursement. This system should be less expensive over the long run, since repair and replacement costs (part of the quality evaluation) would be less. A second possibility would be to reimburse at a higher rate for products that carried extended war-

ranties (excluding normal wear and abuse), placing manufacturers at risk for the durability of their products.

Prescribing and Paying for Significantly Valuable Wheelchair Features Under Government Programs

New technology in wheelchairs that may be significantly valuable to users may not be developed and diffused. When manufacturers have some assurance of a reasonably sized and predictable market for an innovation, they are usually much more likely to implement it. A serious impediment to the diffusion of new technology in wheelchairs is that many prescriptions are written for a "standard wheelchair," which allows reimbursement only for one of the least expensive models available. Since the Federal Government pays for almost half the wheelchairs purchased, its policies affect the industry as well as the patients. Medicare's policies are extremely important, not only for chairs it pays for directly, but also as a bellwether for the private insurance industry.

Officials of the Medicare and Medicaid programs could consider encouraging physicians and therapists to prescribe more sophisticated types of wheelchairs if they substantially improve the user's ability to function independently. The Medicare program could communicate this information in a letter to therapists and dealers who currently receive Medicare reimbursement. At the same time, the Medicare program should be sure that providers are aware of the kinds of features for which Medicare or Medicaid would be willing to pay and the kinds of justifications that these features require. Currently, justification is based on medical necessity, but guidelines could be spelled out. If a chair with some special feature, such as lighter weight or removable armrests, results in significantly better function for its user but is unaffordable for the user, Medicare could encourage the therapist to prescribe and justify it, and the dealer to order it.

Currently, the Medicaid program allows no copayments by a wheelchair user. By contrast, the Medicare program allows copayments for more sophisticated wheelchairs, other than the required 20-percent share by the purchaser, only if the purchaser advances the full price of the wheelchair directly.

Many dealers and manufacturers could offer more convenience and amenity options as "accessories," such as especially comfortable or durable upholstery. If improved seating is therapeutic, it could be so indicated and billed to a third party. If the accessory was purely an amenity, it could be written up and billed to the user as a separate item, but, if ordered at the same time, could be installed on the wheelchair at the factory. For example, cloth upholstery might be offered as an accessory in place of the standard vinyl upholstery. This practice would allow users to customize their wheelchairs with features that could not necessarily be justified on the basis of medical necessity. The cost of a basic wheelchair would still be billed to the insurer and only the accessory billed to the user. To prevent overcharging, Medicare and Medicaid might require that they be notified about the nature and price of such accessories.

For features *prescribed by the therapist*, the extent of justification required by Government and private insurers would entail *tradeoffs between maximizing the independence and comfort of the client and containing cost for the payer*. For example, suppose a handicapped person could be provided either a standard manual wheelchair costing $400 (retail) or a prescription manual wheelchair costing $1,000, the 1983 estimated industry average prices for their respective categories. (Based on estimated annual industry sales of 300,000 and 70,000 units respectively (including rental and institutional chairs), over 75 percent of manual chairs are standard (1).) The prescription chair, however, allows a user to have the design, dimensions, weight, type of armrests, etc., tailored precisely to his or her requirements. The $600 difference in initial purchase cost translates to a differential in annualized cost of about $250 per year. If the prescription wheelchair allowed even a moderate improvement in function, the small investment might appear cost effective.

Physicians and therapists should be encouraged to think carefully about the tradeoffs between cost and performance. To clarify these issues, payers

and prescribers may wish to establish a joint force to write prescribing guidelines for cases that are clear cut; remaining cases would be left to individual judgment.

Subsidizing Selected R&D Activities

Although several manufacturers would like the Federal Government to award them contracts for specified R&D projects, this contracting role must be carefully defined. Appropriate criteria for Government support of R&D might include the following: 1) relatively large social gain, i.e., innovations that substantially improve the user's ability to function independently; and 2) relatively large expected social gain compared to the manufacturer's gain from this innovation. Examples of the latter are development efforts that would be difficult to appropriate by patent, or those where the manufacturing setup cost is modest. Economic theory suggests that in cases such as these, private companies would be reluctant to innovate because the innovations could be copied easily.

Government-supported R&D currently focuses heavily on basic research and on transfer of high technology to wheelchairs. Since manufacturers say that they cannot afford such research, funding agencies may wish to continue supporting it. However, the level of support could be based on the expected utility of results. Market research could be undertaken to determine what is most important to the end users. In addition, it would be useful for agencies that support research to understand how a new product will be paid for prior to committing resources to an R&D investment. Further analysis on the impact of reimbursement policies on purchasing practices is needed to determine whether the products that are developed through Government research will ever reach a significant market.

The general-purpose manual wheelchair seems to be the object of relatively little research, despite the fact that it constitutes the majority of the market. Here, R&D costs for manufacturers and strict price limitations by third-party payers virtually preclude innovation that enhances quality. This chair would seem to be a prime subject for Government R&D, particularly ideas not patentable, such as the use of a novel material in an existing wheelchair design.

Government funding of R&D by manufacturing companies is one way in which new products could be made more readily available to the public. Transfer of technologies from other industries, such as high-performance batteries or microprocessors, could be encouraged through Government funding of R&D in sophisticated wheelchairs. Manufacturers might then make such innovations available at a lower cost to the consumer, since the manufacturer's costs for R&D would be shared by the Government, and the Government could make the process available to competitors. It would be valuable to make market research a component of development work funded by the Government to assure that an adequate market exists for a proposed innovation.

Encouraging and Expediting the Development of Standards for Wheelchair Performance

Although the VA has issued performance standards for its own procurement of manual and power wheelchairs, there are no standards for other purchasers or for the industry as a whole. *In the absence of performance standards, it is not clear whether the less expensive wheelchair which is usually purchased represents a better buy or an inferior product.* If standards are not forthcoming, better information would be useful. If the results of monitoring data described above were made available to dealers and therapists, they and the users would be better able to choose the appropriate chair.

Standards that refer to performance, rather than design, and that are flexible are less likely to stifle innovation. Performance standards could be based on the weight carried, the kinds of stress tolerated by the wheelchair, the frequency of repairs allowed, and other performance issues. Performance issues include safety, battery longevity for power chairs, rolling resistance, and brake design. Penalties for noncompliance by manufacturers could be clearly defined. These penalties could include guidelines for recompensing the in-

jured party in an accident involving a noncompliant chair, as well as stiff fines, or automatic disallowance of Medicare or Medicaid reimbursement.

Responsibility for improving wheelchairs and assuring their safety seems to be shared among all involved parties: Government and independent associations for setting and enforcing standards, manufacturers for thoroughly testing products before marketing, dealers for selling equipment with proven safety, third-party payers for evaluating a product's safety and effectiveness, therapists and physicians for properly assessing and prescribing the wheelchair appropriate for the user's needs and abilities, and consumers for using the equipment correctly. Appropriate actions by all of these parties would minimize wheelchair accidents.

2.
Description of the Device and Its Market

2. Description of the Device and Its Market

TECHNOLOGY OF WHEELCHAIRS

Wheelchairs fall into four broad categories: 1) general-purpose manual wheelchairs, 2) power wheelchairs, 3) manual sports wheelchairs, and 4) power alternatives—other motorized vehicles not shaped like a chair. In this study, the term "wheelchairs" refers to all four types of equipment.

Manual wheelchairs, the most commonly used kind, may be propelled by the user's hands or feet or pushed by another person. They are usually built in a traditional chair shape with two sets of wheels rather than legs. One set, usually located in the rear, consists of large bicycle-type wheels, and the other set is of small casters, usually 5 or 8 inches in diameter.

Power wheelchairs are usually battery powered, with a power supply of 12, 24, or, more recently, 36 volts. Batteries make power chairs much heavier than manual ones (e.g., 180 pounds for the motorized Power Rolls® IV described in ch. 6). Motorized wheelchairs are generally controlled by a hand-operated joystick, which regulates direction and speed. Some control mechanisms, however, are operated by breath, chin or head position, or other nonmanual means.

Manual sports wheelchairs are lightweight and are designed to shift the center of gravity to achieve greater mobility and stability than is possible with general-purpose manual or power wheelchairs. Some chairs are designed for specific sports, such as basketball or racing; others are for general sports use. Features associated with sports wheelchairs may include larger propelling wheels than on general-purpose manual wheelchairs, small handrims, sloping propelling wheels, more durable and efficient bearings and hubs, movable axle positions, and steerable casters. Some of these features are also available as options on nonsports chairs as well.

Power alternatives, which function like motorized chairs but do not look like typical wheelchairs, offer a variety of advantages over power wheelchairs. Most of these models have three wheels and resemble golf carts or motor scooters; some allow travel over terrain that typical wheelchairs do not, such as shallow water or sand and other soft, uneven surfaces. Smaller power alternatives permit greater mobility through narrow doors and aisles. Other models have swivel seats to allow closer approaches to desks and work surfaces. In addition to the physical advantages, power alternatives may provide a psychological advantage because they do not evoke the stereotypical image of a helpless, confined person often associated with standard wheelchairs. They usually require, however, that the user can hold his or her trunk upright with minimal support.

Wheelchairs are available in a variety of sizes to accommodate infants as well as large or tall adults. Some children's models can accommodate growth by changing the legrests and upholstery. Seat heights can be varied to place children at eye or table level with their peers. Such variations in seat height can be helpful for people of all ages who need to use their feet for propulsion. An alternative to foot propulsion and steering is the one-arm-drive device on which different handrims on one wheel control both large wheels independently.

Most wheelchairs have small wheels in casters in the front and large wheels in the rear—a design which makes the chair stable and easy to get in and out of. Some wheelchairs are designed with the large wheels in front and the casters in back. Although less stable, these indoor chairs may make maneuvering over door thresholds easier.

Special features can be added to most chairs to meet the individual's needs. Armrests may be ei-

ther fixed, to provide support, or detachable, to allow side transfers (movement in or out of the wheelchairs accomplished by sliding sideways). They may be designed to allow close approach to tables and desks or to increase the seat width. Legrests are available in a range of styles to allow close approach to a table or to make it easier to fold the chair, elevate a leg, or facilitate transfers. Many manual wheelchairs are lightweight and fold for transport in a car. Optional safety features include: heel and toe loops, rear and front anti-tipping devices, hill-climbing adaptations that prevent back-sliding, and easy-to-grip handrims.

Recent or expected design innovations include: voice-controlled motorized wheelchairs; stair-climbing chairs that have tanklike belts rather than wheels; and lighter weight, more durable chairs.

SAFETY AND EFFECTIVENESS

To date, there are no comparative studies of the safety and effectiveness of different wheelchairs. The only information is from case reports and impressions by those involved with wheelchairs—primarily consumers and therapists—and the results of evaluative testing on specific wheelchairs by the Veterans Administration Prosthetics Center.

In general, people with greater mobility are able to use a wider variety of wheelchairs more safely and effectively than those with more serious disabilities. One important factor in predicting safe use of wheelchairs is the person's trunk stability and control; without this, an individual may have difficulty sitting in the chair without special body support and operating a wheelchair or its locks when bending or reaching is required. Accessory supports, such as pommels and straps, are available for those people who have problems with trunk instability. However, these do not improve the effectiveness of the wheelchair if the person needs to lean or bend to operate any part of it.

USERS, PURCHASERS, AND PRESCRIBERS OF WHEELCHAIRS

In its 1982 report, *Technology and Handicapped People*, the Office of Technology Assessment (OTA) reported that there were about 9 million Americans with lower extremities missing, paralyzed, or impaired (36). Of those people, approximately 1,168,000 (one American in 200) used wheelchairs. Users in 1977 included 650,000 non-institutionalized persons (33) and an additional 518,000 residents of nursing homes. The number of nursing home users is expected to grow to 584,800 by 1985, an annual growth rate of 1.5 percent (25).

The number of wheelchairs in use exceeds the number of users. People dependent on wheelchairs often have more than one chair, either for different uses, such as sports, or, especially, for times when one is being repaired. A 1982 survey by the Paralyzed Veterans of America found that 72 percent of the respondents had more than one wheelchair (16). This percentage may be greater than that for the overall population of users, because most of the respondents obtained their wheelchairs from the Veterans Administration (VA), which typically supplies people with two wheelchairs, whereas other agencies generally supply only one.

The type of wheelchair bought often depends most on the physical therapist and the dealer. A physician's prescription is generally required for third-party reimbursement for a wheelchair, its accessories, or its special features, but physicians are frequently unaware of which special features and accessories are available and appropriate for the patient. The therapist usually makes these decisions based on the user's medical, personal, and environmental needs. (Most insurance companies,

however, will pay only for those accessories that are medically necessary.)

The therapist or dealer is also usually the one to measure the user to determine the wheelchair size needed. Measurements determine the optimal height of the seat from the floor, the height of the backrest, the length of the armrests and legrests, and the width and depth of the seat. Dealers who have floor models may ask the purchaser to sit in the chairs to determine which is most comfortable, but accurate measurements are the best guarantee of a proper fit. An improper fit can cause back problems and pressure sores and can make safe operation of the wheelchair difficult.

The prescription may or may not specify the wheelchair brand. If it does not, the therapist or dealer makes the decision. Most dealers carry only a few of the larger brands of wheelchairs. The decision to carry a specific brand or model is based partly on past service and product quality and partly on the amount of profit. If dealers buy a high volume of wheelchairs from the manufacturer, they usually receive a discount off the wholesale price. At any given time, dealers may have in stock only the models on which they were given the best price. In addition, lower priced products carry a greater percentage markup. Most manual wheelchairs have a 40-percent markup over dealer's wholesale price, and motorized wheelchairs a 30-percent markup.

Most users do not special order a wheelchair model not in stock at the dealer or manufacturer. Those who are purchasing their first chairs often are not aware of the options. Even those who are purchasing replacement wheelchairs may be aware only of the chairs that they have had in the past.

The dealer's comments may be the only evaluation the user ever hears, which makes the dealer's personal recommendation and training very important. Most dealers' recommendations are based on a combination of what wheelchair they believe is best for the user, plus the reimbursement and profit that they will receive on different wheelchairs. Proper recommendations require training in fitting techniques and knowledge about the consequences of different impairments.

Sales of wheelchairs are expected to increase as a result of current efforts to control rising hospital costs. Because of decreasing lengths of stay in hospitals, more patients may need to buy or rent wheelchairs for use at home. Patients at home obviously require their own wheelchairs, whereas hospitalized patients can share chairs (4).

COSTS

Purchase Costs

General-purpose manual wheelchairs are the least expensive type. List prices of general-purpose manual wheelchairs recorded in the ABLEDATA System generally ranged from $400 to $900. Most power wheelchairs cost between $2,000 and $3,000, and power alternatives cost from $950 to $3,000. Sports wheelchairs vary in price from $800 for a racing model to $1,200 for a general sports model, significantly more than most general-purpose manual chairs (37).

One major purchaser, the VA, paid an average of $336 for a manual wheelchair and $2,216 for a power wheelchair in fiscal year 1982 (40). Costs vary with the type of chair bought. The VA Outpatient Clinic in Boston bought chairs primarily for use outside rather than inside the facility. There, the average manual wheelchair cost $579 (41).

In addition to the manufacturer's base purchase price, there may be significant customization costs. These costs vary according to what is required. The customization needed may be as simple as adding a swing-away legrest or as complex as adding an entire life-support system complete with respirator and intravenous drip bottle holder.

Maintenance and Repair Costs

Maintenance of a wheelchair is a substantial component of the cost of wheelchair use. Data

from the VA Outpatient Clinic in Boston indicate the magnitude of maintenance costs. During fiscal years 1981 through 1983, it performed or authorized an average of 380 wheelchair repairs per year on all chairs in use. During that same time, it purchased an average of 137 wheelchairs per year (114 manual or sports and 23 electric) (41).

In this study, the authors assumed that the overall life expectancy of a VA wheelchair (manual and power combined) is 3.5 years, the midpoint of the generally reported lifetime (2 to 5 years) and a reasonable estimate according to the VA prosthetics official contacted. The rates of chairs purchased and repaired were stable over the fiscal years studied. The average lifetime of 3.5 years per wheelchair was used to calculate that each wheelchair received 0.8 repairs (380 ÷ [3.5 × 137]) per year. At an average 1982 direct cost of $190 per repair ($140 for parts and purchased services, and $50 for technician salary and fringe benefits), each chair required at least $150 in repairs during a single year, or $525 over its lifetime (undiscounted). This almost equals the average purchase price of a manual wheelchair.

Although these VA repair data are not divided into manual and power chair costs, the actual repair costs were probably lower for manual wheelchairs and higher for power wheelchairs. These costs do not include repairs paid by sources other than the VA or the VA's indirect costs (administration, building upkeep, equipment, etc.), which together could double the aggregate repair cost. For example, according to a survey by the Paralyzed Veterans of America, the VA performed only 42 percent of repairs on respondents' chairs (16). (It was not reported, however, whether all respondents were eligible for repairs by the VA.)

Medsger (17), using data from the Berkeley Center for Independent Living, found that power wheelchairs required an average of $900 of maintenance a year. If the average life of a power wheelchair is 4 years, the $3,600 lifetime cost of maintenance (4 × $900, undiscounted) is 1.6 times its purchase price, a relationship similar to the VA pattern. A 1982 survey by the Paralyzed Veterans of America showing six or more repairs per year reported by the top category (16 percent of respondents) (16) also underscores the frequency of repairs.

Total annualized cost conveniently combines initial purchase plus maintenance into an expression of the annual overall costs of wheelchair use. This measure converts the capital cost of initial purchase of a wheelchair into an annualized capital cost. To effect this conversion, first the cumulative present value (CPV) factor over the expected life of the wheelchair is needed. (This is also termed the "present value of an annuity.") The CPV factor is based on the lifetime of the wheelchair and the discount rate, an interest rate that measures the time value of money invested in the initial wheelchair purchase.

For illustration, using the discount rate of 10 percent per year recommended for some Government cost-benefit analyses (39), the CPV factors for 3 to 4 years are:[1]

Lifetime (years)	*CPV*
3.0	2.487
3.5	2.828*
4.0	3.170

*Interpolated.

Annualized capital cost is obtained by dividing the initial purchase price by the CPV. Total annualized cost, then, is annualized capital cost plus average maintenance costs. To apply these methods to the direct cost data from the VA Outpatient Clinic (mostly manual wheelchairs), the life expectancy was set at 3.5 years, as described previously, and, therefore, for all chairs:

$$\text{Annualized capital cost} = \frac{\text{initial purchase price}}{\text{CPV}} = \frac{\$579}{2.828} = \$205$$

and

$$\text{Total annualized cost} = \text{capital} + \text{maintenance} = \$205 + \$150 = \$355 \text{ per year.}$$

[1] If r is the discount rate (as a decimal), and n is the expected lifetime (as a whole number), then:

$$\text{CPV} = \frac{1}{1+r} + \frac{1}{(1+r)^2} + \cdots + \frac{1}{(1+r)^n}$$

For example, for a discount rate of 10 percent and 3 years (r = 0.10 and n = 3), we have:

$$\text{CPV} = \frac{1}{1.1} + \frac{1}{(1.1)^2} + \frac{1}{(1.1)^3} = 2.487$$

This figure is 73 percent more than the annualized capital cost alone. If the initial cost of the power wheelchairs analyzed by Medsger was $2,216 (the national VA average for power chairs [40]), then for power chairs:

$$\text{Annualized capital cost} = \frac{\$2,216}{3.170} = \$699$$

and

$$\text{Total annualized cost} = \$699 + \$900 = \$1,599$$

or 129 percent more than the capital component alone.

This annualizing procedure is equivalent to amortizing a mortgage or a capital asset over its expected lifetime. The annualized capital cost is slightly higher than the amount that would be obtained by straight line depreciation. Depreciation computes the money needed each year to replace a capital asset; annualized capital cost also includes foregone interest on the money tied up in a wheelchair that could have been invested.

This technique provides a way of comparing different models to determine which is lower in total annualized cost. To illustrate, hypothetical repair profiles were developed for an "inexpensive" and a "medium-priced" wheelchair (table 1). On the assumptions that each would have an expected life of 3.5 years and that repairs for the inexpensive chair would be more frequent, the total annualized cost of the inexpensive chair ($338) would actually be higher than that for the medium-priced chair ($309) because of higher annual maintenance and repair costs. In this illustration, the greater initial investment would pay off.

To place the repair record of wheelchairs in perspective, the lifetime frequency of major repairs was estimated for several other types of durable medical equipment (table 2). Wheelchairs ranked second highest, which underscored users' concern.

Table 1.—Illustrative Comparison of Total Annualized Costs of an "Inexpensive" v. a "Medium-Priced" Wheelchair

	Inexpensive wheelchair	Medium-priced wheelchair
Given data:		
Initial purchase cost (new)	$320[a]	$590[b]
Expected lifetime (years)	3.5	3.5
Average annual maintenance and repair costs[c]	$225	$100
Calculated results:		
Cumulative present value factor	2.828	2.828
Annualized capital cost	$113	$209
Total annualized cost	$338	$309

[a] Cost for an inexpensive, all-purpose wheelchair.
[b] Cost for a manual wheelchair with anti-flutter sealed bearing and flutter adjust system. Magnesium wheels added for $50.
[c] Both models assumed to require annual replacement of tires, biannual replacement of seat upholstery, and miscellaneous repairs and adjustments. The inexpensive model is also assumed to require replacement of axle, casters, and spokes.

SOURCE: Initial purchase costs are from Invacare price list. Repair costs are hypothetical.

Table 2.—Comparative Lifetime Repair Data of Selected Medical Equipment[a]

Item	Number of repairs	Number of items supplied	Repairs per item
Braces, all	36	228	0.16
Eyeglasses	176	7,542	0.02
Home dialysis equipment	11	5	2.2
Artificial legs, all	604	137	4.4
Wheelchairs, all	383	128	3.0

[a] Number of repairs and items are for fiscal year 1982 at the VA Outpatient Clinic. Repairs per item would equal lifetime number of repairs in steady state (numbers of repairs, items supplied, and items in use were constant).

SOURCE: Derived from U.S. Veterans Administration, *AMIS Report for VA Outpatient Clinic for Fiscal Year 1982*, Boston VA Outpatient Clinic, Boston, MA, 1982.

PRIVATE PAYMENT SOURCES

An estimated 90 to 95 percent of all wheelchair purchases are at least partially funded by third parties (Government or private insurers); only 5 percent are paid totally by the user (19). Over half of wheelchair purchases are at least partially paid for by Government sources including Medicaid, Medicare, and the VA. In particular, in 1976, 11 percent were reportedly paid for by the VA (17). (See ch. 3 for a fuller discussion of the Government's role as a purchaser of wheelchairs.)

Private Insurance

To illustrate private insurance coverage for wheelchairs, the authors contacted Blue Cross of Massachusetts, the largest private insurer in the Commonwealth of Massachusetts. Insurance coverage for rental or purchase of wheelchairs depends on whether the policy covers durable medical equipment. If it does, reimbursement is usually for 80 percent of the reasonable charge, using a formula similar to that used by Medicare. Only those wheelchairs and accessories that are prescribed by a physician are covered (11).

Blue Cross of Massachusetts, for example, will pay for rental of a wheelchair up to the allowable reimbursement for purchase of a similar wheelchair. Repairs of rented chairs are covered as part of the rental agreement. Blue Cross will not pay, however, for repairs of purchased wheelchairs. A Blue Cross benefits representative usually decides whether a wheelchair should be purchased or rented.

Blue Cross pays for the least costly wheelchair that meets the user's physical needs. For a new, more costly model of a wheelchair to be covered, it must have a unique feature of medical benefit not available on a less costly model. Depending on the policy, purchase of electric wheelchairs was covered in 1983 for up to $2,711; power alternatives are covered up to $2,700.

New products are reviewed for coverage by Blue Cross of Massachusetts by its Medical Review Board. The Physicians Advisory Panel may be consulted in cases where the medical benefits of a new product to an individual subscriber are unclear.

Health Maintenance Organizations

The Harvard Community Health Plan, which serves over 100,000 members throughout the Boston area, was studied as an example of a health maintenance organization. The Health Plan will pay in full both rental and purchase costs for medically necessary wheelchairs for members. The user's physician must complete a form documenting the need. The particular wheelchair and features needed may be decided on by the physician, physical therapist, or nurse practitioner. The Benefits Coordinator then reviews the need and recommends rental or purchase based on the expected length of use. Wheelchair rentals are reviewed monthly to verify continuing need.

SIZE OF THE MARKET

Aggregate annual sales of wheelchairs in the United States, including imports and exports, were estimated to reach $107.5 million in 1983, measured by shipments from the manufacturers. This is an annual increase of 11.7 percent over the 1980 figure of $77.2 million (25).

A market study done by Invacare Corp. estimated the total market to be $126 million in 1982 (valued at cost to dealers and other major purchasers). Thirty percent, or $37.7 million, was attributed to the home care market. (Home care wheelchairs tend to be manual, fairly standard models, for people with limited mobility.) Another 30 percent was attributed to institutions, including hospitals, nursing homes, and rehabilitation centers. (Institutional wheelchairs are also standard, manual chairs, used almost exclusively for transport within the institution.) The remaining 40 percent ($50 million) was attributed to rehabilitative care, for active and short-term users who are neither homebound nor institutionalized. (Rehabilitative chairs may be from any of the four basic categories and cover a wide range of customization and cost.)

Invacare's estimate of the total number of units sold in 1982 was tentative, ranging from 250,000 to 364,000. Market share estimates in terms of numbers of chairs showed 38 percent for home care, 35 percent for institutional care, and 27 percent for rehabilitative care. On a price-per-unit

basis, home care chairs are least expensive, and rehabilitative wheelchairs are most expensive (see table 3).

Based on an estimate of 338,000 wheelchairs bought in 1982, another breakdown shows about 125,000 rental chairs, 125,000 institutional chairs, 55,000 manual chairs for active users, 15,000 power wheelchairs, and 18,000 depot chairs for the VA (see ch. 3) (3).

Table 3.—Market Size and Shares of Wheelchair Uses

	Units	Dollars	Price/unit[a]
Total	330,000-360,000[b]	$125.7 million	$349-$381
Home care	38%	30%	279-305
Institutions	35%	30%	299-326
Rehabilitative	28%	40%	508-554

[a]The range given is based on the range in total number of units sold. All figures are rounded to the nearest dollar.
[b]Number of wheelchairs of all types sold based on central estimates.
SOURCE: Market study by Invacare, Elyria, OH, 1983.

MARKET STRUCTURE

Reviews of product descriptions in the National Rehabilitation Information Center's computer bank, ABLEDATA, identified 53 manufacturers of wheelchairs. However, the market appears to be reasonably concentrated, for one-quarter of the manufacturers accounted for 71 percent of the products (see table 4). This measure uses the number of different model lines of wheelchairs or power alternatives listed for each manufacturer in ABLEDATA as a proxy for a manufacturer's size. Seven manufacturers are located outside of the United States, and six are outside of North America; of these, two have U.S.-based distributors. This concentration should cause the market to behave as an oligopoly.[2]

[2]Oligopoly refers to a situation in which there are a limited number of sellers of a product. Competition in price and design may be limited not by any explicit agreements, but by the knowledge that an action by one firm will prompt a reaction by the others.

The large manufacturers gain oligopoly power from their distribution patterns. National distributorships enable consumers to find knowledgeable local dealers and obtain repairs and replacement parts quickly. In wheelchairs, as with other equipment, service can be a major factor in choice of brand.

Prior to 1978, Everest & Jennings, Inc. (E&J) acted virtually as a large single seller, controlling 90 percent of the prescription wheelchair market (17). In 1978, settlement of an antitrust suit brought against E&J by the U.S. Department of Justice imposed some limits on E&J's market power. At the same time, E&J relocated its headquarters and plant. The combined effect of these two events caused E&J severe difficulty in meeting its orders on time. As a result, smaller companies were able to gain a greater share of the market, increasing competition and stimulating innova-

Table 4.—Concentration of Manufacturers of Wheelchair Products[a]

Rank group for size of manufacturer	Number of products listed for a manufacturer	Number of manufacturers	Cumulative number of products	Cumulative percent of products	Cumulative number of manufacturers	Cumulative percent of manufacturers
1	32	1	32	18.2%	1	1.9%
2	15	1	47	26.7	2	3.8
3	14	2	75	42.6	4	7.5
4	9	1	84	47.7	5	9.4
5	8	2	100	56.8	7	13.2
6	6	1	106	60.2	8	15.1
7	5	1	111	63.1	9	17.0
8	4	2	119	67.6	11	20.7
9	3	2	125	71.0	13	24.5
10	2	11	147	83.5	24	45.3
11	1	29	176	100.0	53	100.0

[a]Manufacturers ranked from the one with the most products (32) to the least (1) in ABLEDATA (see app. A).
SOURCE: Derived from U.S. Department of Education, National Institute of Handicapped Research, National Rehabilitation Information Center, ABLEDATA System, 1983.

tion. Since 1978, E&J's sales have declined slightly in absolute terms, but markedly when adjusted for inflation. In 1983, Invacare Corp. overtook E&J in the quantity of wheelchairs sold, although E&J remained first in dollar volume of wheelchair sales. Invacare and E&J combined sales accounted for 70 percent of wheelchair sales dollars in 1983 (1).

Prior to 1978, wheelchair imports were almost nonexistent, but the antitrust suit the Department of Justice settled against E&J in that year lifted the import restrictions E&J had imposed on its foreign subsidiaries. Nevertheless, imports remain a tiny part of the wheelchairs sold in the United States. This is evidenced by the lack of a category number under the Tariff Status of the United States for wheelchair imports. The director of wheelchair marketing at Invacare estimated imports to account for 1 percent of 1983 gross sales measured in dollars ($1.3 million) and more than 1 percent measured in units sold. In his opinion, this share is rising due to the recent wave of imports from countries with "preferred developing country" status (23). Products made in these countries can be imported duty-free and are significantly less costly than U.S.-made wheelchairs of similar quality.

Wheelchair exports from the United States are large enough to merit their own classification (Schedule B, No. 7270120). Exports of wheelchairs and wheelchair parts in 1982 were $9.6 million (34).

PRIVATE RESEARCH AND DEVELOPMENT INITIATIVES

Most wheelchair manufacturers do their own research and development (R&D), calling it crucial to the success of their companies. R&D reportedly focuses on improving current wheelchair design, rather than on developing completely new products. For instance, those companies whose major products are lightweight wheelchairs are interested in developing even lighter weight products (see ch. 5).

Only one manufacturer surveyed referred to work on process innovations (new manufacturing techniques) rather than product innovations, but the lack of response about process innovation probably resulted from the slant of the questions toward product innovation.

3.
Roles of the Federal Government

3. Roles of the Federal Government

AS A MAKER OF NATIONAL POLICY

Accessibility to the Handicapped

Federal laws and regulations to protect wheelchair users are few in number, general in purpose, and weak in enforcement. Most policies have their legal basis in Section 504 of the Rehabilitation Act of 1973 (Public Law 93-112), intended to prevent the exclusion of physically or mentally handicapped people from any program or activity receiving Federal money. One part of this broad act requires that all publicly owned or federally assisted buildings, both residential and nonresidential, be accessible to people with physical disabilities.[1] Buildings predating these laws need not be brought up to standards, unless they undergo alterations that affect accessibility. In that case, the alterations must make the building accessible.

The Urban Mass Transportation Administration (UMTA) has exhibited a continuing commitment, but ambiguous philosophy, toward assuring the mobility of disabled persons. The UMTA has not decided whether accessibility means access to all mass transit systems or access to public places via special transportation services. In May 1979, the UMTA ruled that half of all buses must be wheelchair-accessible by 1989. That ruling is currently being challenged by local transit authorities and some persons with disabilities who believe that special separate transportation services are more effective and cost efficient (24).

[1]Applicable Federal Government regulations are: "Policies and Procedures for the Enforcement of Standards and Requirements for Accessibility by the Physically Handicapped," 24 CFR 41; and "Standards for Design, Construction, and Alteration of Publicly Owned Residential Structures," 24 CFR 40. The standards of accessibility for residential structures are those written by the American National Standards Institute, "Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped, No. A117.1, 1980." The Secretary of Housing and Urban Development is responsible for designing plans to bring buildings into compliance when voluntary compliance is not possible. The Architectural and Transportation Barriers Compliance Board is responsible for any further necessary action.

Effects of Government Policies on Wheelchair Design

Federal standards for accessibility to the handicapped have influenced wheelchair design somewhat and apparently also have been shaped by it. Door width standards, for example, have been designed to accommodate the average-sized wheelchair. The Veterans Administration (VA) recommends a minimum door width of 36 inches, based on a typical wheelchair width of 27 to 29 inches from the outermost points of the wheels and handrims (20). The Architectural and Transportation Barriers Compliance Board recommends basing door widths on an average wheelchair width of 26 inches.

By making more services and facilities accessible to persons with physical disabilities, the Federal Government may be encouraging handicapped persons to be more active and involved in public, thereby stimulating the demand for lighter weight and more esthetically designed wheelchairs so they can be more active.

State and local policies also have had an effect on wheelchair design, for manufacturers must consider the relevant policies of all States and municipalities in which they sell their product. Fire codes are most important; they affect the fabric, foam, and glue used in wheelchair upholstery. California and Boston city fire codes tend to be the most stringent. No Federal fire codes exist, but the Food and Drug Administration (FDA) is expected to establish fire standards within the next few years (8). National standards will relieve the manufacturers' burden to be aware of and compliant with the policies of 50 different States.

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AS A PURCHASER

As mentioned above, Federal and State Government funds are involved in over half of all wheelchair purchases. The policies of the three main Federal purchasers, Medicare, Medicaid, and the VA, differ from one another, and among regions or States within each purchasing program.

Medicaid

Medicaid policies are determined by each State within Federal laws and regulations. At the Federal level, Medicaid policies are established by the Health Care Financing Administration (HCFA). Massachusetts, which has one of the more comprehensive Medicaid programs, is used as an illustration of State policies. In Massachusetts, Medicaid pays an "adjusted acquisition cost" for all wheelchairs determined to be medically necessary. This adjusted acquisition cost includes the dealer's cost (excluding associated costs such as shipping and handling) plus a percentage increase, typically 30 percent (12). As in most other States, this cost is divided almost equally between the State and Federal Governments.

To receive reimbursement, a dealer must file a Prior Authorization Form, completed by both the prescribing physician and the dealer, documenting the medical need for the wheelchair and the type of wheelchair recommended. The form is reviewed and reimbursement is approved, denied, deferred pending receipt of additional information, or approved with modifications. A decision must be made within 15 days of receipt of the Prior Authorization Form. In cases where a 15-day delay would jeopardize the user's health or delay discharge from a hospital, an immediate decision may be requested by telephone, with written documentation to follow. The more expensive the wheelchair and accessories recommended, the stricter the review.

Medicaid in Massachusetts will rent and repair wheelchairs for beneficiaries whose needs are temporary; it also covers repairs of purchased wheelchairs and provides a temporary replacement. If the rental period exceeds 3 months, or if the cost of the repair will exceed $35, the Prior Authorization Form must be filed. Authorization of repairs is rarely denied, so the dealer may feel safe in making the repair before formal authorization is received.

Federal policy dictates that if a Medicaid reimbursement is obtained, the dealer must accept it as payment-in-full. This is different from Medicare, in which the patient may pay coinsurance, a deductible, and possibly the excess over Medicare's allowed reimbursement. For users covered under both Medicare and Medicaid, Medicaid pays the coinsurance and deductible as defined by Medicare.

In fiscal year 1982, the Massachusetts Medicaid program bought 1,069 wheelchairs, of which 212 (20 percent) were electric, at a total cost (including some accessories) of $639,000. Separately purchased wheelchair accessories, such as legrests, desk tops, and armrests, cost $166,000. Medicaid's average cost to purchase, customize, and equip one wheelchair was $752. This is the sum of purchase costs plus accessory costs divided by the number of wheelchairs bought. Costs for manual and electric wheelchairs could not be separated.

There were an additional 1,069 months of wheelchair rentals (the numerical agreement with purchases is coincidental) at a total cost of $47,000. Medicaid paid for 8,492 repairs, at a total cost of $455,000. Repairs figure almost as prominently in these data as in the VA data reviewed earlier on the assumption that purchase and repair costs remained constant and the lifetime is 3.5 years. On the basis of the method described earlier, the average annualized cost per chair is $266 for capital and $122 for maintenance, or $388 total. (Annual amounts were extrapolated from data for the months of January, March, July, and October [7].)

Extrapolating from Massachusetts data, national Medicaid expenditures for wheelchair purchases, rentals, and repairs were extrapolated at about $50 million in 1982.[2]

[2]This estimate was approximated from the Massachusetts figures on the assumption that other States' Medicaid programs purchase wheelchairs at a similar rate, relative to their 1980 census population, and at similar costs. This figure was computed using the Massachusetts Medicaid expenditures for wheelchairs, a State population of 5.737 million persons, and a national population of 227.7 million (32).

Data from California generate consistent extrapolations. Extrapolations from data for October through December 1982 indicate that California's Medi-Cal (Medicaid) program paid $190,000 over 1982 for rental of wheelchairs and accessories (an average of 612 items under rental each month) and $3.15 million for purchasing 7,192 wheelchairs and accessories over the same period (2). As the California population was about 24 million (32), the national Medicaid expenditure on purchase and rental (but not repair) of wheelchairs and accessories extrapolates to $32 million. If repairs were added, the total would probably be similar to that from Massachusetts. National extrapolations based on both of these States may be overestimates, however, since Massachusetts and California eligibility and reimbursement policies may be less restrictive than many other States.

A new product is approved for coverage in Massachusetts at the State level by Medicaid administrators on the advice of a consultant. The product rarely receives blanket approval for Medicaid payment; most frequently, a product is approved for payment only for a particular patient. The patient must petition for payment if the device is one that is not usually approved for payment. The decision often rests on the patient's persistence in pursuing payment (12). The addition of a product to the list of approved products comes only after many individuals have sought and received payment for it.

Medicaid places substantial responsibility on the wheelchair provider to limit costs. Its Durable Medical Equipment Manual (sec. 106 CMR 409.432) states:

> (A) The provider is responsible for making reasonably certain that the durable medical equipment or medical/surgical supplies furnished are the most cost effective . . . .
>
> (B) Before purchasing equipment or supplies, the provider must make a reasonable effort to purchase the item from the least-costly reliable source by comparing prices charged by different suppliers for comparable items.

Careful attention to the cost-effectiveness requirement would consider purchase costs, repair costs, and performance. Most providers would probably not be able to conduct cost-effectiveness studies, and would probably focus on part B of the regulation, seeking to furnish the wheelchair with the lowest purchase price.

Medicare

Medicare, like Medicaid, is a program of HCFA. Medicare is an insurance program for persons aged 65 and over who are eligible for Social Security or railroad workers' benefits and for disabled people. Unlike Medicaid, Medicare generally sets coverage policies at the national level. HCFA contracts with local intermediaries (insurance companies), which are responsible for processing and adjudicating claims based on medical necessity and reasonableness of cost. Medicare does not evaluate new equipment itself for coverage decisions but relies on the Office of Health Technology Assessment in the Public Health Service for coverage evaluations.

Medicare payments for wheelchairs are limited to 80 percent of the allowable charge,[3] which is determined yearly for each provider by the intermediary, and is the lowest figure among the actual charge for the item, its customary charge in the previous year, and the prevailing charge for that type of item the previous year. The actual charge is the billing for the particular item. The customary charge is the individual provider's most common charge for that item in the previous year. The prevailing charge, which measures the charges for a type of item for all providers in a geographic area, is set at the 75th percentile of charges submitted to Medicare for that type of item from the geographic area in the previous year. Providers whose charges are low and stable for their area thus receive almost 80 percent of their charge from Medicare. Providers that charge higher prices receive from Medicare a lower percentage of their billed charge. One dealer estimated that his allowable charge lagged behind his actual charge by 5 years, and he indicated that most accessories are not reimbursable (18). Power wheelchairs are paid for on an "individual consideration" basis.

[3]Medicare beneficiaries are responsible for the remainder of the price, but dealers may have difficulty collecting their total charges if the patients' share is high.

Dealers have two ways of receiving greater payment for products sold to Medicare recipients. First, they may bill the user instead of Medicare. In that case, the user must pay the full price, submit a claim to Medicare for 80 percent of the allowable charge, and pay the difference. Second, dealers can rent the wheelchair to the user on a long-term basis. Medicare places no time limit on the length of a rental and will pay for 80 percent of the rental fee up to the purchase price. This alternative imposes no added cost on the user. Reimbursement for rental chairs is approximately $35 per month for manual wheelchairs and $150 per month for electric wheelchairs (18).

Medicare has been trying to reduce rental costs by stringently reviewing all long-term rentals. So far, however, regulations have not been completed and promulgated, so they are not legally binding. Regulating long-term rentals will not necessarily reduce costs, since Medicare will be required to pay for rentals while a determination is made as to whether the wheelchair should be bought or rented.

All wheelchairs and accessories reimbursed by Medicare must be prescribed by a physician and must be medically necessary. Power wheelchairs must be prescribed by a specialist in physical medicine, orthopedic medicine, or neurology who has determined that "the patient is unable to operate a wheelchair manually" (Public Law 95-216). The need for a specially sized wheelchair, based on the patient's physical build or on the structural feature of the place of use, may be determined by the supplier and need not be included on the prescription.

Products that do not fit any existing category of reimbursable durable medical equipment may not be covered under Medicare, and creation of a new category requires a congressional amendment. Section 1861(s)(6) of the Social Security Act was amended in 1977 to allow coverage of "durable medical equipment including . . . . wheelchairs (*and devices designed to serve the same or similar purpose as that performed by a wheelchair*. . .") (italicized parenthetical phrase was that added by the amendment). Representative Griffin, from the Michigan district in which Amigo Sales is located, sponsored the amendment. At that time, Amigo was the only manufacturer of a three-wheeled power alternative. Interestingly, the Amigo had been covered under Medicare prior to 1976, at which time the decision was made to discontinue coverage, necessitating the amendment (6).

National data on costs to Medicare of wheelchair purchases, rentals, or repairs could not be obtained.

Veterans Administration

The VA is reportedly the largest Federal purchaser of wheelchairs, although the authors' calculations made for this case study suggest that Medicaid is larger when State and Federal shares are combined. In 1976, the VA accounted for 11 percent of all wheelchair purchases (in dollars) (17). The VA pays the full cost of two wheelchairs for those veterans who medically require them and who meet the VA's eligibility requirements. Eligibility depends primarily on the extent and service-connected status of the veteran's disability.

A physician must determine the need for a wheelchair; the rehabilitation therapist or the prosthetics technician determines the type of wheelchair needed based on environmental and physical factors. Provision of a power wheelchair requires approval by a committee at the VA facility. Veterans engaged in registered sports, such as wheelchair basketball, may have their sports chairs supplied by the VA. Once it supplies a wheelchair, the VA also makes or pays for needed repairs to an eligible veteran's chair and provides a substitute wheelchair for use while the veteran's own chair is being repaired, if necessary.

VA medical centers may purchase wheelchairs for their own and veterans' use from one of three categories. The first category is a low-priced manual chair used for transportation within hospitals and clinics. Called a "depot" chair, it is purchased in large quantities under competitive contract (currently with the Invacare Corp.) and stocked in regional depots. This method generally provides a wheelchair most quickly and least expensively.

Second, a wheelchair may be purchased from those listed on the Federal Supply Schedule compiled by the General Services Administration (GSA). Chairs listed must fit a "commercial item description" (CID)—a description of a wheelchair design based on the design of a currently available model. If an appropriate CID does not exist, a manufacturer may petition the VA or GSA to write a CID to fit its product. A description must be approved by the U.S. Department of Commerce and the GSA before it is finalized. Within each CID, wheelchairs are given priority based on price.

Finally, a VA facility may purchase a wheelchair for an individual veteran if it is not on the Federal supply purchasing list. A waiver from the VA Central Office in Washington, DC, is necessary if the cost exceeds $1,000.

The VA has long set design or performance standards for most wheelchairs it buys. Historically, the VA's standards have been written with a specific wheelchair in mind, usually an Everest & Jennings, Inc. (E&J) model (17). In 1977, performance standards were written that focused more directly on function rather than design specifics. Standards for power wheelchairs are currently under revision, based on the conclusions of the Wheelchair Workshop III, cosponsored by the VA (26). A child's wheelchair made by E&J Canadian has been identified that comes close to meeting these standards, and modifications to make a similar adult chair are underway. If the VA decides that the adult chair meets the standards, it will become the VA model. Manufacturers who will want to obtain VA contracts may have to make products similar to the E&J wheelchair.

Effects on Innovation

The policies of these three reimbursement programs may hinder innovation in wheelchair design and diversity. Medicaid pays in full, but only for the least costly chair needed. Medicare pays only part of the allowable charge, which may itself be less than the actual charge. A supplier who accepts Medicare payment on assignment receives 80 percent of Medicare's allowed charge directly from Medicare. The supplier must agree, however, not to demand in total more than Medicare's allowable charge. This policy creates an incentive to encourage the patient to buy the least costly model that satisfies his or her prescription. In addition, the large, established companies are the best able to compete on the basis of price. The problem, however, is that the patient's prescription may not fully describe his or her needs.

Prior to the promulgation of performance standards for manual chairs in 1977 and for powered chairs in 1981, the VA's procurement standards may have protected the user's safety, but they appeared to function mostly in the interest of the major manufacturers (29,30). When VA standards were written in accord with E&J specifications, products were often evaluated on the basis of how closely they conformed to E&J's model. Also, manufacturers interviewed for this case study indicated difficulty in learning the protocols that the VA would use to evaluate a new product. This uncertainty has made innovation risky, as manufacturers do not know whether their products will meet VA standards and, if they do not, whether those standards might be modified.

Federal payers currently focus their payment decisions on purchase price without considering maintenance and repair costs. Although small manufacturers tend to have a competitive disadvantage in purchase price, due to diseconomies of scale, they may be superior in quality, and hence less expensive over the product's useful life. No data are available, however. Decisions made on the basis of total annualized cost would appropriately reward more durable models. Such analyses might open the door to smaller manufacturers, making the market less oligopolistic and more competitive.

AS A REGULATOR

Classification of Wheelchairs

The Center for Devices and Radiological Health of the FDA is charged with classifying all medical devices according to their potential risk to users and the degree of regulation required. Class I, general controls, encompasses devices for which general controls are sufficient to provide reasonable assurance of safety and effectiveness. These general controls are required of all three classes. Class II, performance standards, contains devices for which general controls are considered insufficient to assure safety and effectiveness, and information exists to establish performance standards. Class III, premarket approval, applies to devices for which Class I general controls are insufficient, information does not exist to establish a performance standard, *and* the device supports life, prevents health impairment, or presents a potentially unreasonable risk of illness or injury (35).

Manual wheelchairs intended for short-term, indoor use are Class I. All other manual wheelchairs, power wheelchairs, standup wheelchairs, and three-wheel motorized devices (power alternatives) are considered Class II. Stair-climbing wheelchairs are Class III devices (31). Ninety days premarket notification and good manufacturing practices are required for all medical devices including wheelchairs. Manufacturing practices regulate conditions in the factory and bookkeeping procedures, but do not affect the products. To date, no standards have been written for any Class II products.

Development of Standards

Naturally, dealers' incentives to maintain their reputation motivates them to sell only safe and effective products; however, without stringent established guidelines, safety and effectiveness can be determined only through experience. Only the alternatives to power wheelchairs have undergone extensive testing to earn qualification for third-party payments. A dealer may attempt to minimize the possibility of selling a hazardous product by purchasing only from established companies, but even this is no guarantee. For example, in 1971, E&J sold the "Remarkable Mark 20," an electric wheelchair designed for outdoor use by people with minimum hand coordination. It caused several potentially serious accidents (17). To prevent such accidents, the industry would need performance standards for safety, testing to determine whether standards are met, and enforcement to assure that standards are followed.

The lack of standards may also bear on the repair rate of wheelchairs. A wheelchair's need for repairs causes not only inconvenience and expense, but also can be a source of accidents. Accidents due to crossbars' breaking, for example, may be attributed to metal fatigue brought on by extended hard use of the chair, or to defective materials or welding. User complaints registered with the FDA's Center for Devices and Radiological Health include wheelchairs catching fire and wheels falling off (17). Manufacturers and the FDA blame the need for repairs on improper use by the consumer (17), but standards might improve wheelchair durability.

Wheelchair performance standards are currently being written by a task force of the Rehabilitation Engineering Society of North America. This task force is an independent group composed of seven wheelchair researchers, three wheelchair manufacturer representatives, two consumers, one FDA representative, one VA representative, one occupational therapist experienced in wheelchair prescription, and one surgeon specializing in spinal cord injuries. Although the standards will not be officially available for several years, manufacturers who are participating in the writing of the standards have access to the proposals and can consider them in their product design (27).

When completed, the standards will be adopted by the American National Standards Institute, although they will be voluntary only. The strongest force for compliance may be the pressures of the international marketplace. Rehabilitation Engineering Society of North America, which is the U.S. representative to the International Standards Organization (ISO),[4] is designing its standards in

[4]The ISO, headquartered in Geneva, Switzerland, sets performance and safety standards for dozens of types of scientific and medical devices.

coordination with the ISO standards, also in preparation. To the extent that Western European and South American countries adopt ISO standards as law, those U.S. companies with large export businesses will have a strong incentive to comply with the standards of the Rehabilitation Engineering Society of North America (14).

Investigation and Resolution of Complaints

If a person believes a wheelchair is defective, he or she can register a complaint with the FDA Center for Devices and Radiological Health, Device Experience Branch, which conducts a search for prior complaints against the product and summarizes the product's history. Only complaints that have been registered with the FDA are included in that history; rarely is a privately handled complaint included. The complaint is assigned a priority rating based on the reason for it. Cases that resulted in death receive highest priority. Those cases where serious harm could have or did occur receive the next highest rating. Both of these types of cases must be resolved within 30 days. The least serious level of complaint, a routine investigation, has no time limit (15).

The suggested priority and the summarized product history are sent to the Center's Regulatory Guidance Branch, where they are evaluated and action is taken. Full investigations are conducted by the field manager responsible for the geographic area in which the manufacturer is located. The field manager inspects the manufacturing plant and product specifications to decide whether the plant is capable of manufacturing to specifications. Assembly and quality control are evaluated, as is the quality of the raw materials. If the complaint is of the lowest priority, the inspector may choose not to investigate until the required biennial inspection (15).

After completing the investigation, the field manager sends an evaluation and recommendation to the Regulatory Guidance Branch, which makes a final decision. FDA prefers voluntary corrective action by the manufacturer rather than direct government intervention. Depending on the nature of the problem, the manufacturer may correct it at its source or may issue a recall of the affected products. Compliance is monitored by followup inspections, typically 30 days for a correction of an in-house problem and 3 months for a product recall.

If the manufacturer refuses to take appropriate action voluntarily, several options are available to FDA. FDA can require the manufacturer to give public notice, repair or replace defective wheelchairs, or give a refund to the user if there exists an unreasonable risk of harm to public health. FDA may petition the court to order a recall of devices that it determines are "misbranded" or "adulterated." In theory, devices that fail to meet applicable standards could be recalled on these grounds. Finally, "red tag" injunctions may be issued, prohibiting shipment of products from individual warehouses. In practice, these actions are rarely carried out because they are slow and cumbersome for FDA, and certainly unpopular with the manufacturer.

The most powerful leverage actually at FDA's disposal is the threat of a public announcement that could accompany such legal actions alleging that a product is defective, misbranded, or adulterated. To avoid such harmful publicity, manufacturers usually voluntarily recall a product that FDA considers defective or comply with other requests for corrective action (22).

AS A SUPPORTER OF RESEARCH, DEVELOPMENT, AND EVALUATION

National Institute of Handicapped Research

The National Institute of Handicapped Research (NIHR), sponsors research of interest to people with disabilities. Its $36 million research budget for fiscal year 1983 included not only $750,000 exclusively for wheelchairs, but also other programs, such as work station modifications for disabled persons, that relate indirectly to wheelchair users (28). The NIHR Rehabilitation Engineering

Center at the University of Virginia is researching such areas as power systems, seating, and human factors in wheelchair use. It is also assisting the Rehabilitation Engineering Society of North America in developing standards of wheelchair performance and design (see section "As a Regulator"). It supports two regional institutes to evaluate innovations, disseminate new product ideas, and stimulate the manufacture of all types of devices for handicapped persons.

The National Aeronautics and Space Administration

Through its Langley Research Center, the National Aeronautics and Space Administration is currently devoting about $50,000 annually in professional time and expenses to apply state-of-the-art engineering techniques to wheelchair design as part of its mandate to demonstrate terrestrial applications of technology (42).

Veterans Administration

The VA's Rehabilitation R&D program includes wheelchair research and development projects based on the VA-cosponsored Wheelchair III Workshop (26), as well as a collaborative effort with the National Aeronautics and Space Administration involving computer simulation. Goals include design improvements targeting the wheelchair base, power base, and stability. In fiscal year 1983, the VA provided $511,000 for rehabilitation R&D projects on the power wheelchair, seat cushions, anti-roll back design, and a feedback controller.

Over two decades, the VA Prosthetics Center encouraged innovation by demonstrating that new types of wheelchairs were technologically possible, safe, and, most importantly, that there was a significant market for them—the VA. For example, the VA Prosthetics Center's work with power wheelchairs in the early 1970s demonstrated that electric wheelchairs could be safely used at speeds greater than a slow walk, and that they could be designed to be used on rough terrain. This encouraged wheelchair manufacturers to make chairs with those capabilities. Efforts centered around lightweight sports wheelchairs had similar effects (13). These occurrences support the hypothesis that manufacturers will innovate if they feel secure that their products will be purchased by Government agencies and reimbursed by third-party payers. The VA Prosthetics Center in New York City is now responsible for evaluating wheelchairs and other rehabilitative products.

AS A JUDGE OF PRODUCT LIABILITY

Product liability is a risk to any manufacturer. If a wheelchair-related injury or death occurs, the victim or family may file a lawsuit for financial compensation in Federal or State court against the manufacturer and others involved. However, the lack of standards for the wheelchair industry clouds the issue of responsibility.

One manufacturer claimed that product liability suits have replaced medical malpractice suits as the most common and most profitable lawsuits filed today. Many manufacturers choose to settle out of court, rather than incur the costs of a court battle. Others will incur the court expenses, if they believe the incident was not the fault of their product, to uphold their principles and discourage frivolous suits. Regardless of how the manufacturer chooses to resolve complaints filed, the costs are high.

The fear of possible product liability suits is a major obstacle to innovation, according to several of the manufacturers surveyed. This fear is greatest for an entirely new product and less for the majority of innovations, which are modifications of existing products.

All wheelchairs, especially power and power alternative wheelchairs, require a certain level of coordination to operate safely. Manufacturers

specify which impairments complicate the safe operation of their product with the hope of protecting users and avoiding responsibility for accidents to users with those impairments. This process may, however, shift the responsibility for safety to the dealer who sold the wheelchair and to the doctor and therapist who ordered it. Because of this fear of a product liability suit, some doctors and therapists may hesitate to prescribe or recommend a new product whose safety has not been proven.

4.
Overview of Innovation

4.
Overview of Innovation

ECONOMIC THEORIES OF INNOVATION

For this report, an "innovation" is any product or product modification that substantially improves the quality or decreases the cost of a product, while introducing a technology, material, or concept not previously found in any similar product on the market. Although this definition includes process innovations (changes in the means of production), this case study is most concerned with product innovations (changes in the final product), especially those that introduce a new concept into wheelchair design.

A primary tenet of microeconomics holds that individuals and firms act to maximize their own utility (satisfaction) or profit. Firms make products for which they expect to receive financial rewards. Although theorists agree on this general goal, they disagree as to its effect on innovation. They also disagree with the commonly held belief that perfectly competitive firms must innovate to remain competitive. This latter belief mixes the economic idea of perfect competition with the everyday meaning of "competition." By definition in economic theory, perfectly competitive firms have no reason to innovate because products are not differentiated and because the same technologies for production are available to all firms.

In 1915, Taussig proposed that innovations result from attempts to fulfill an expressed demand with the expected reward of profit. Hicks recognized that once the product exists, the incentive must change from reaping profit to reaping continued and increasing profits. In 1932, he proposed that the task of innovation is to decrease the cost of production, hence increasing the amount of profit (10).

Schumpeter characterized the role of large corporations with considerable market power, and with large research laboratories as the source of innovation of the day. Many economists using static economic theories would predict that industries with a large number of small firms would encourage innovation. By emphasizing the role of large firms, Schumpeter explicitly remarked that such fragmented industries with many small firms would not innovate for two reasons: First, in such a structure, firms find it difficult to get necessarily high profits because imitations would be almost immediate, thereby eliminating excess profits and destroying the incentive to innovate.

Second, firms in this structure would not have the size to support the requisite industrial research laboratories. Some readers of Schumpeter are under the impression that he advocated monopoly as the source of innovation. Rather, he viewed large firms, whether or not they were in industries with single dominating firms (monopolies), as rivals competing to fulfill expressed consumer demands with the expectation of profits (21). Galbraith agreed, noting that for firms that do not compete on price, innovation offers an alternative means of increasing market share and profits (10). Empirically, Kamien and Schwartz found that in general industries with intermediate degrees of competition have had more innovations than those at the extremes, although there are certain industries on either side that show high degrees of innovativeness (10).

As mentioned earlier, the wheelchair market seems to fit the intermediate category by having a few large firms that have a very large market share and several smaller firms. The two largest wheelchair manufacturers, Everest & Jennings, Inc. (E&J) and Invacare Corp., control approximately 70 percent of the market in dollar sales, but about 50 other firms are also listed in the ABLEDATA System as wheelchair manufacturers. The industry also seems to fit into the intermediate range because, as economists would predict, buyers recognize the large companies' brand names more readily than small companies' names and are willing to trust a name they recognize and know to be established.

MANAGEMENT AND GOVERNMENT PERSPECTIVES

Innovation is a costly and risky process, especially for small firms. Several of the manufacturers interviewed for this study (see ch. 5) cited the high cost of innovation as the largest impediment to the introduction of new products. While the Federal Government could encourage innovation through contracts or favorable tax treatment, the efficiency of these approaches requires careful study. In aggregate, expenditures by industry for all types of health R&D are substantial. In 1982, industry spent $3.4 billion and the Federal Government spent $5.0 billion (38).

Since industry spent such a large sum, this finding might suggest that Government support of industry R&D is not necessary. However, there are times when Government funding is appropriate. The wheelchair market is small and diverse. R&D efforts by industry focus on active users, the most lucrative segment of the market. Government funding might be useful in areas that would complement existing research, such as the large, general-purpose manual wheelchair market and the market for certain specialized rehabilitative wheelchairs. The manual wheelchair may be neglected because there are strict price limitations by third-party payers making it difficult for suppliers to charge a premium for added quality. The specialized rehabilitative wheelchair may be neglected because development costs are too high and the potential market is too small. For both types of wheelchairs, however, added features may be worth the costs.

It may also be useful to target Government funding toward the areas where the results are not patentable (e.g., a new use for an existing material). Such subsidy could be awarded directly as grants and contracts by such agencies as the National Institute of Handicapped Research or indirectly through amending the Internal Revenue Code to create tax incentives (generally through accelerated depreciation) for targeted R&D activities.

Some economists believe that the conflicts over proprietary rights to information obtained through Government-supported research make Government cooperation unattractive to manufacturers (10). The manufacturers surveyed indicated that this is not a major problem. It seems likely that contracts could be negotiated that would satisfy both the manufacturer and the Government and would benefit the consumer by increasing the rate of innovation.

When questioned about patent rights, wheelchair manufacturers felt that they were not of major importance because the firms cannot count on having the 17-year period of sole design that patents are supposed to provide. Lawsuits alleging patent infringement are seen as an expensive stalling tactic, designed to give a product a strong foothold in the market before competitors can make a similar product. It was agreed that making a similar product that does not infringe upon a patent is not difficult for a determined competitor. Being first on the market was considered to be a significant advantage.

5.
Survey of Wheelchair Manufacturers

5.
Survey of Wheelchair Manufacturers

SURVEY METHODS

Eleven wheelchair manufacturers chosen from a list developed from products listed in the National Rehabilitation Information Center's data bank, ABLEDATA, on about July 1, 1983, were interviewed between July 15 and August 31, 1983. This list might be imperfect due to lags in updating ABLEDATA about new or discontinued products, but was the best available. Ten of these manufacturers were selected through a sequential sample designed so that the larger the number of products listed for the manufacturer, the greater its chance of being selected (see app. A). This sampling process made the sample less prone to bias from any ability to update the list. (Most updates would probably apply to small manufacturers.) The principal investigator wrote a letter to manufacturers selected for the survey describing the study and kinds of information sought (history of past innovations and descriptions of R&D activities), and inviting them to participate. When one company declined to participate due to time constraints, a replacement was chosen through the process of sequential selection.

None of the companies chosen at random manufactured power alternatives to wheelchairs. Amigo Sales, Inc., was then chosen as a representative of that group on the basis of its previous work with the U.S. Congress' Office of Technology Assessment (OTA) and the availability of its information on the products. This brought the total to 11 companies surveyed. The officials of selected manufacturers were then interviewed by telephone according to a semi-structured set of questions (see app. B).

INNOVATIONS OF THE PAST DECADE

Respondents were asked to identify their most significant innovations over the last 10 years. Many such innovations focused on increasing the mobility of wheelchair users (table 5), particularly the active user (table 6) who is apt to want a chair that is easy to use (lightweight and easy-rolling); transportable (lightweight, easy to disassemble, folding); durable; and safe to use outdoors. Dynamic brakes, which keep the wheelchair from gaining speed when going downhill, are a helpful safety device to an active person.

Most manufacturers interviewed identified higher cost of an innovative product as the largest impediment to marketing new devices, but surprisingly only one manufacturer specifically identified low cost to the buyer as an advantage to an innovation. One possible explanation is that manufacturers do not perceive reducing the cost of their product as a significant concern to wheelchair users, due to the high percentage of wheelchairs paid for by third-party payers. Perhaps Medicare's prevailing charge system creates a price umbrella. As copayments and competition increase, as seems likely, manufacturers may begin to be more concerned with lowering product cost.

All of the innovations identified by the manufacturers were currently available at the survey date, possibly because manufacturers are eager to sell their present products or because they did not think of or care to mention products that are not current. It may also be that most of the innovations identified are so recent that they have not yet become obsolete. Indeed, all five innovations for which dates reported were developed within the last 4 years (see table 7).

Most of the innovations identified were improvements of existing products (table 8). Seven innovations were based on personal experience and identification of unmet needs; three of them

Table 5.—Wheelchair Innovations, 1973-83

Code[a]	Innovations	Features/advantages
Manual wheelchairs:		
M1a	lightweight manual	• lightweight • disassembles
M1b	lightweight manual	• serves active user • lightweight • low-friction tires and bearings
M2	compact folding chair	• folds in one piece • lightweight • fits compact car trunk
M3	free-rolling chair	• lightweight • stainless, noncorrosive frame
M4	stainless chair	• stainless, noncorrosive frame • conventional design • improved bearing construction • lightweight • durable construction
Power wheelchairs:		
P1	proportional control box	• high-technology joy stick • solid-state circuitry • infinite variability in speed and direction
P2	folding electric chair	• lightweight • electric • folding
P3	lightweight electric	• electric • lightweight • disassembles
P4	power wheelchair	• dynamic brakes • automatic steering correction • lightweight
Sports wheelchairs:		
S1	sports chair	• lightweight • 16 different seating positions • adjustable seat/back heights • lifetime warranty on frame
Power alternatives:		
PA1a	three-wheel alternative	• three wheels • disassembles • dynamic braking • narrow • usable in planes • extendable wheelbase • adds stability • optional elevating seat
PA1b	three-wheel chair	• swivel seat • disassembles • narrow • three wheels • controls on handlebars • "looks fun"
Accessories:		
Ac1	telescoping leg rests	• infinite number of positions • better support
Ac2	solid seat	• better support
Ac3	conversion kit for E&J power drive	• increased speed • durable • simple to service • low cost

[a]Innovations identified through the survey were categorized as being for manual wheelchairs (M), power wheelchairs (P), sports wheelchairs (S), power alternatives (PA), or wheelchair accessories (Ac). Within each category, the products were randomly assigned code numbers. Small letters after an innovation code are used to differentiate between products of similar description.

SOURCE: D. S. Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app. B).

also used existing technology. Only 4 of the 15 innovations used technology from other fields. They were from simpler fields, such as bicycle and stretcher manufacturing. Many people in Government R&D centers believe that current high technology is not being fully utilized by the wheelchair industry. The survey found no instances of high technology transferred to wheelchairs. The case study of the Power Rolls® IV, however, showed an application of state-of-the-art electronics. It incorporated a wheelchair controller with self-correcting steering on slopes (see ch. 6). This survey suggests that existing R&D or marketing are often inadequate for the transfer of high technology.

Table 6.—Frequency of Features or Advantages in Wheelchair Innovations, 1973-83

Feature or advantage	Frequency[a]
Lightweight	9
Easily disassembles	4
Serves active user	3
Durable	2
Folding	2
Dynamic brakes	2
Low-friction brakes/bearings	2
Better support	2
Narrow width	2

[a]Frequency was measured only for those features or advantages with a frequency greater than 1.

SOURCE: D. S. Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app. B).

Table 7.—Length of the Development Process

Innovation code[a]	x[b]	Prototype date	y[c]
Manual wheelchairs:			
M1a		NA	
M1b	4 mo.	9/82	11 mo.
M2	12 mo.	1979	>12 mo.
M3		NA	
M4		NA	
Power wheelchairs:			
P1		NA	
P2		NA	
P3		NA	
P4	8 mo.	9/80	12 mo.
Power alternatives:			
PA1a	18-24 mo.	1981	12 mo.
PA1b		NA	
Sports wheelchairs:			
S1	12 mo.	11/79	<12 mo.
Accessories:			
Ac1		NA	
Ac2		NA	
Ac3		NA	
Median	12 mo.	9/80	12 mo.

[a]Categories of innovations were for power wheelchairs (P), manual wheelchairs (M), power alternatives (PA), sports models (S), and accessories (Ac). Within each category, the products were randomly assigned numbers. Small letters after an innovation code differentiate products of similar description, but different manufacturers.
[b]"x" is the length of time, in months, from the conception of the innovation idea to the making of the prototype.
[c]"y" is the length of time, in months, from the making of the prototype to the first commercial delivery of the product.

SOURCE: D. S. Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app. B).

Table 8.—Source of the Innovative Idea

Innovation code	Personal experience[a]	Existing product[b]	Technology transfer[c]
M1a	—	X	—
M1b	—	X	X
M2	X	—	—
M3	X	X	—
M4	—	X	—
P1	X	X	—
P2	X	X	—
P3	—	X	—
P4	—	X	—
S1	X	—	X
PA1a	—	X	—
PA1b	X	—	—
Ac1	—	X	X
Ac2	—	X	X
Ac3	X	X	—
Total	7	12	4
Percent[d]	46.7%	80.0%	26.7%

[a]"X" indicates that idea was derived from personal experiences with wheelchairs or from identification of unmet needs.
[b]Innovation was a modification or improvement of an existing product.
[c]Innovation was based on a transfer of technology from another health care product or another field.
[d]Percent, based on 15 innovations, for which the innovation is at least partially attributable to each source.

SOURCE: D. S. Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app. B).

SOURCE OF FUNDING FOR INNOVATIONS

The R&D efforts behind the innovations studied were all privately sponsored. None of the manufacturers interviewed received any Government funding, although some of them do cooperative work with universities on Government-funded research projects. Several respondents expressed interest in Government funding of R&D. They did not seem to feel that the loss of control over patent rights, which often accompanies Government funding of projects, was a major problem. The advantage that comes from being first on the market with a new product was said to be much more important than patent rights.

REIMBURSEMENT BY GOVERNMENT PAYERS

All of the innovations identified by the study are now reimbursable under Medicare and Medicaid, if they are medically necessary and prescribed by a physician.

The Veterans Administration (VA) takes longer to approve a new product for purchase than it takes to approve one for reimbursement by Medicare and Medicaid. Only 10 of the 15 innovations

identified through the survey are covered by the VA. Of those 10, two are reimbursable only with a waiver. One of those two meets VA procurement standards but is not on the Federal Supply Schedule; the other does not meet standards (table 9).

Table 9.—Eligibility of Innovations for Purchase by the VA

Innovation code	Yes	No	Innovation code	Yes	No
Manual wheelchairs:			***Sports wheelchairs:***		
M1a	X		S1	X	
M1b	X		Total	1	0
M2		X	***Accessories:***		
M3		X	Ac1	X	
M4	X		Ac2	X	
Total	3	2	Ac3	X[a]	
Power wheelchairs:			Total	3	0
P1	X		Grand total	10	5
P2		X	Percent of innovations	67%	33%
P3		X			
P4	X				
Total	2	2			
Power alternatives:					
PA1a		X			
PA1b	X[a]				
Total	1	1			

[a]Product is not on the Federal Supply Schedule purchasing list, but may be bought in individual cases.

SOURCE: D. S. Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app. B).

R&D EFFORTS

All but one of the companies surveyed have their own R&D departments. The one relies solely on outside firms for its R&D. Four of the companies use outside firms in addition to in-house staff. The outside companies generally develop a particular part to be used in the wheelchair, for example a lighter weight alloy or a new controller. The manufacturers pointed out that they and their subcontractors do not do basic research but develop new ways of putting together known materials and ideas.

Although most manufacturers said R&D was a critical part of their operations and success, some were hesitant to specify the size of their R&D operations. The largest R&D budget identified was 5 percent of gross annual sales (see table 10). The limited quantitative responses indicated a median of 4 percent of sales and 9 full-time equivalent employees devoted to R&D.

The areas of R&D tended to parallel the kinds of products already under production. Only a few manufacturers mentioned development in a part of the market in which they did not currently have products.

The most common area of R&D mentioned involved utilization of lighter and stronger materials. Also important were development of better control systems and more esthetic design (table 11).

Table 10.—Location and Size of R&D Departments

Manufacturer code[a]	Location[b]	Size of department: Percent of sales	Size of department: FTE[c]	Size of department: Qualitative
1	IH	—[d]	7	—
2	IH	—	9	—
3	CT	NA[e]	NA	NA
4	IH	5%	—	—
5	IH, CT	4%	—	—
6	IH	NA	NA	NA
7	IH	—	10	—
8	IH, CT	NA	NA	NA
9	IH	—	—	"the main structure of the company"
10	IH, CT	>2%	—	—
11	IH, CT			"absolutely crucial"... now more than ever..."
Median		4%	9	

[a]Manufacturer code numbers were randomly assigned to the companies surveyed. The codes used are constant for this and all other tables.
[b]IH indicates an in-house R&D department; CT indicates contractual arrangements with other companies.
[c]FTE is full-time-equivalent employees.
[d]Dash indicates data are expressed in other terms.
[e]NA indicates no data are available on size of department.

SOURCE: D. S. Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app. B).

Table 11.—Types of R&D Efforts

Manufacturer code	Areas of R&D	Manufacturer code	Areas of R&D
1	• control systems • posture support systems • curb-climbing wheelchairs • wheelchair design	6	• airline models • rehabilitation models
2	• style; appearance • attachment to motorize a manual chair	7	• stronger, lighter materials • electric wheelchairs
3	• NA[a]	8	• NA[a]
4	• stronger, lighter materials • more efficient design • stronger construction • more cost-effective production procedures	9	• stronger, lighter materials • decreased rolling resistance • increased durability and longevity
5	• improved control mechanisms • stronger, lighter materials • style; appearance	10	• improved control mechanism • refinement of current products
		11	• style; appearance • stronger, lighter materials • lower rolling resistance

[a]NA indicates no data available.

SOURCE: D. S. Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app. B).

TARGETS OF MARKETING CAMPAIGNS

Dealers are most influential in diffusing an innovation; 9 of the 11 manufacturers surveyed aim their marketing campaigns at dealers. Six of them also target the end user, five the institution (hospital, rehabilitation center, or nursing home), four the foreign markets, three the VA, and two the therapist. Clearly, more than one market may be targeted simultaneously.

It was surprising that only two mentioned the physical therapist because it is often the therapist who decides what kind of chair the user is to have. One explanation for this fact may be that the manufacturers meant to imply marketing to therapists when they said they market to institutions. Another possible explanation is that, although therapists often decide what features are needed on

an individual user's wheelchair, it is the dealer who often decides which brand is ordered. Unless a company makes a wheelchair with unique features of which they need to inform therapists, there may be very little return on these marketing efforts (table 12).

Table 12.—Marketing Procedures: At Whom Is the Marketing Aimed?

Manufacturer code	Therapist	Dealer	Institution	User	VA	Exports
1	—	X	X	—	—	—
2	—	X	X	X	—	—
3	—	—	—	X	—	—
4	—	X	X	—	—	—
5	X	X	—	X	X	—
6	—	X	—	—	—	—
7	—	X	—	—	—	X
8	—	—	X	X	—	—
9	—	X	—	—	X	X
10	—	X	—	X	—	X
11	X	X	X	X	X	X
Total	2	9	5	6	3	4
Percent[a]	18%	82%	45%	55%	27%	36%

[a]Percent of the 11 manufacturers surveyed who market to each group.

SOURCE: D. S. Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app. B).

MARKETING TOOLS

Of the 11 manufacturers surveyed, 10 said they introduced new products at trade shows, 7 depend on their sales force, 6 advertise in professional and trade journals, 5 advertise in user journals, and 2 rely heavily on word of mouth (table 13).

Ironically, although the most frequently used marketing device is trade shows, many of the manufacturers added that the shows were not very helpful in marketing their products. They serve to show what the competition is doing and to introduce new products, but not to make large sales. Actual sales take place outside of the trade shows, mostly through personal contact between sales representatives and dealers or institutions.

Advertising in professional and trade journals educates therapists and dealers on what is avail-

Table 13.—Tools Used to Market a New Product

Manufacturer code	Word of mouth	Trade shows	Professional journals[a]	User journals[b]	Sales representatives
1	—	X	X	—	X
2	X	X	—	—	X
3	—	X	—	X	—
4	—	X	—	—	X
5	—	X	X	X	X
6	—	X	X	—	X
7	—	X	—	—	X
8	—	X	—	X	—
9	—	—	X	—	—
10	X	X	X	X	—
11	—	X	X	X	X
Total	2	10	6	5	7
Percent[c]	18%	91%	55%	45%	64%

[a]Professional journals include trade journals for therapists, hospital supply catalogs, etc.
[b]User journals include magazines for persons with disabilities (e.g., *Paraplegia News*), catalogs, and newspapers.
[c]Percent of 11 manufacturers surveyed who use each marketing device.

SOURCE: D. S. Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app. B).

able and builds brand-name recognition. Advertising directly to the user is useful for small companies with products that fall outside of the usual range, e.g., three-wheel power alternatives and sports chairs. These products are not usually prescribed and not a regular part of a dealer's stock. Users may have to request that a dealer order them; but if enough orders are placed, the dealer may decide to stock the item. Word of mouth is also a useful advertising tool for these smaller, less traditional companies.

OBSTACLES TO MARKETING

The largest single impediment to marketing a new product is its cost, according to 8 of the 11 manufacturers surveyed (table 14). "Cost" includes the cost of the R&D needed to develop the new product, the cost of setting up production for a new product, and, most significantly, the cost of the marketing process itself.

Three of the manufacturers also identified communication as a major obstacle to marketing a new product. The best communication is through personal contact with sales representatives who can demonstrate and educate. That is a very costly, limited process, given the dispersed locations of therapists, dealers, and users. Advertisements in professional, trade, and user journals are not as good because they reach not the entire market, but only those people with a special interest in wheelchairs. Not all users read user journals, and most first-time purchasers do not. One of the most widely read user journals, *Paraplegia News*, is read almost exclusively by veterans.

Three manufacturers said that the medical community is slow to accept new concepts and designs in wheelchair technology. Part of this reluctance hinges on safety issues. For instance, doctors and therapists may hesitate to prescribe a power wheelchair that runs at a higher speed than most, because they are at risk of malpractice suits if a person is injured while using a device. The manufacturers are aware of this but believe that doctors and therapists are unwilling to prescribe new devices even for people who want them and are capable of using them safely.

Brand-name identification was also mentioned as a marketing impediment for smaller companies. This is less of a problem for manufacturers of unique products than for those who make a more

Table 14.—Factors That Are the Largest Impediments to Marketing a New Product

Manufacturer code	Cost of product	Communication[a]	Medical acceptance[b]	Brand identification[c]	Third-party payment[d]
1	—	X	—	—	—
2	X	X	X	—	X
3	X	—	—	—	—
4	X	—	—	X	—
5	X	—	—	X	—
6	X	—	—	—	—
7	X	—	—	—	—
8	—	X	—	—	—
9	X	—	—	—	X
10	X	—	X	—	—
11	—	—	X	—	X
Total	8	3	3	2	3
Percent[e]	73%	27%	27%	18%	27%

[a]Communication between manufacturer and others (dealers, therapists, doctors, users) is limited and difficult, hindering diffusion of innovations.
[b]Products that vary greatly from the norm are slow to be accepted by the medical community and hence are not prescribed. Diffusion is hindered.
[c]Strong brand-name identification makes it difficult to get people to try a product from a company with which they are not familiar.
[d]Third-party reimbursement is difficult to get for new products. It is also often slow in coming, making dealers hesitant to sell products for which they may not be reimbursed, or that are more expensive than the reimbursement received. Money is lost during the lag time between billing and receipt of reimbursement.
[e]Percent of the 11 manufacturers surveyed who identified each item as an impediment to marketing.

SOURCE: D. S. Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app. B).

standard product. Given two products that appear to be essentially the same in function and design, it is more likely that a therapist will prescribe and a dealer will stock brands that are familiar to users. Manufacturers also said that brand-name identification is more of a problem with first-time users than with people who are making a repeat purchase. Active users tend to be aware of the products around them and to compare features. On a second purchase, the user may have enough information to request a particular brand of wheelchair, whereas the first-time user depends almost entirely on the therapist and dealer to make that decision.

Third-party reimbursement policies are an obstacle to marketing as well. Products that do not fall into established categories may not be reimbursable at all or only at a rate below cost. Dealers are hesitant to sell products on which they do not make enough profit. Under Medicare, they may choose not to accept third-party assignment and to bill the user directly for the full cost. This practice is also not a guarantee of full payment, as the user may not be able to afford the price or may choose to go to a different dealer where third-party assignment is accepted. The lag time involved in obtaining third-party reimbursement for more expensive or less standard products may also discourage dealers from selling them. Long lag time may result from a claims review process that may approve all purchases of inexpensive, standard models as a matter of course but review all purchases of more expensive, more innovative wheelchairs very carefully.

Although most manufacturers carry product liability insurance, one manufacturer surveyed believed that the high cost of such insurance curtails innovation by keeping profits low. His company, therefore, focused on product improvement, rather than on development of entirely new products. Although such a focus will not lead to major breakthroughs, it usually produces results more quickly and at lower cost than development of new products.

ROLE OF STANDARDS

Almost half of the manufacturers surveyed (5 of 11) said that they take existing or proposed standards of outside organizations into account when designing their products (table 15). Three of the five identified the VA standards as important. Of these three, an importer from Britain considers both VA and British standards; one takes proposed Rehabilitation Engineering Society of North America standards into account; and one considers only VA standards. Two indicated that

Table 15.—Role of Voluntary Standards in Manufacturers' Design of a New Product

Manufacturer code	Yes	No	Don't know	Which ones?
1	—	X	—	—
2	—	X[a,b]	—	—
3	—	—	X	—
4	—	X[a]	—	—
5	X[a]	—	—	VA
6	X	—	—	VA, British standards
7	X[a]	—	—	—
8	X	—	—	RESNA
9	X	—	—	—
10	—	X	—	—
11	—	X	—	—
Total	5	5	1	
Percent[c]	45%	45%	9%	

[a]Products are manufactured to the company's own standards, which are said to be more stringent than any existing or proposed standards.
[b]Standards change too often and are too difficult to understand for it to be financially feasible to use them.
[c]Percent of manufacturers surveyed who gave each response.

SOURCE: D. S. Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app. B).

their internal standards were more stringent than existing or proposed standards.

Five of the companies stated that they do not take external standards into account, with one adding that existing standards are too confused and confusing to make them worth considering. One other manufacturer did not know what role standards played in the development of its products, since the wheelchair was designed by an outside firm.

VA standards were the most frequently mentioned, both by those who use them and those who do not, probably because they are the only currently written standards. Manufacturers hoping to obtain a VA contract obviously must consider VA standards.

Reactions to the idea of industry-wide standards were mixed. Some manufacturers disliked the idea because they felt the standards would be set too low; they are already manufacturing products to conform to more rigorous standards than they expect to see adopted. If low standards are adopted, they felt that products that meet the standards but are of lower quality and cost than their products would gain a competitive advantage. Other manufacturers, who also believed they are making a high-quality product, welcomed the idea of standards because they believed it would force the lower quality competitors to improve their products, thus benefiting the users. Standards would raise the cost of cheaper products, thereby decreasing the price differential and eliminating some of the current competitive advantage the lower quality manufacturers may have. Regardless of what effect manufacturers thought standards would have, most felt that they would be lower than current technology makes possible.

EFFECTS OF OTHER FEDERAL POLICIES ON R&D

When asked about the effect of Government policies on R&D, three respondents said they were not influenced by any other Government policies, two of them were unsure, and four of them said that they were subject to other influences (table 16). For two of those last four, the relevant agency

Table 16.—Presence of Government Policies That Affect R&D

Manufacturer code	Yes	No	Don't know	Which ones?
1	—	X	—	—
2	X	—	—	Government funding of R&D. The company cannot compete, has a disincentive to fund its own R&D.
3	—	—	X	—
4	X	—	—	FDA—good manufacturing practices, quality control, complaint monitoring.
5	X	—	—	Product liability laws. HCFA reimbursement and approval processes for new, innovative products.
6	—	—	X	—
7	X	—	—	FDA—good manufacturing practices.
8	—	X	—	—
9	X	—	—	Standards have an indirect effect on product design.
10	—	X	—	—
11	X	—	—	VA specifications—the company hesitates to make anything that they cannot sell to the VA.
Total	6	3	2	
Percent[a]	55%	27%	18%	

[a]Percent of 11 manufacturers surveyed who gave each response

SOURCE: D. S. Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app. B).

is the Food and Drug Administration (FDA). Although the FDA has not yet written any standards, companies are subject to "good manufacturing practice," which pertain mostly to recordkeeping procedures. In addition, the FDA investigates complaints that come through their office and may choose to monitor quality.

Interestingly, one small manufacturer (#2) felt that R&D by Government agencies was a disincentive for a small company to fund its own R&D. A small company cannot compete with the level of funding and amount of Government R&D and hesitates to invest large amounts of money and time into R&D only to have a Government agency come out with the same product sooner, according to this manufacturer.

PARTICIPATION IN OBTAINING REIMBURSEMENT

Six of the eleven companies surveyed participate in getting their products approved for third-party payment (table 17). Five of these six focus their efforts on getting VA approval and contracts. One of them aids individual users in getting VA payment for their wheelchairs but does not have a VA contract. Two of them have participated in getting Health Care Financing Administration (HCFA) approval of their products. One has participated in getting approval from an agency other than HCFA or the VA. The remaining five manufacturers do not participate.

Table 17.—Active Participation in Getting Product Approved for Third-Party Payment

Manufacturer code	Yes	No
1	—	X
2	X[a b c d]	—
3	X[b]	—
4	X[a]	—
5	X[a c]	—
6	X[a]	—
7	—	X
8	—	X
9	—	X
10	—	X
11	X[a]	—
Total	6	5
Percent[e]	55%	45%

[a]Company participates in getting VA approval of their product.
[b]Company may participate in getting VA payment for their product in individual cases.
[c]Company has participated in getting HCFA approval of their product.
[d]Company has participated in getting reimbursement from parties other than HCFA and the VA.
[e]Percent of manufacturers surveyed who gave each response.

SOURCE: D. S. Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app. B).

In general, it is not necessary to petition for HCFA approval of a product. As long as the product can be classified in an existing category of durable medical equipment, it is not necessary to get special approval. When the Amigo was first designed, it was not classified as a wheelchair. As discussed above, a congressional amendment was necessary to obtain coverage. Companies that have made similar products since then have been assured of HCFA coverage.

A company may wish to create a new coverage classification when its product can be covered under an existing category but is so much more costly than other items in that category that reimbursement to dealers would be minimal. An example might be a curb-climbing wheelchair. Although this device might be classified as a power wheelchair, its cost is so much greater than most other power chairs that the reimbursement rate would discourage dealers from selling it. For example, under Medicare, the product might have an allowable charge of $1,500 or $2,000, while its actual cost could be $10,000. If a special category could be created for it, then reimbursement would be based on its cost, and the disincentive to selling it would be removed. However, the cost and time involved in petitioning for the new classification may be substantial.

6.
Case Studies of Innovations

6.
Case Studies of Innovations

CASE 1: PAST INNOVATION: INVACARE CORP.'S POWER ROLLS® IV

Description

The Power Rolls® IV, made by Invacare, was chosen as the subject of this case study because of its demonstrated improvement in performance, its capture of a significant market share, and Invacare's cooperation.[1] One model is shown in figure 1.

The Power Rolls® IV introduced dynamic braking, regenerative braking, and self-correcting steering. Dynamic braking is the ability to maintain a constant speed (not accelerate) on a downgrade. Regenerative braking means that the batteries are wired to recharge themselves during braking. The self-correcting steering keeps the wheelchair from veering to one side when it is on an uneven surface. This wheelchair is also lighter than many similar wheelchairs.

Development

An ambitious new group of investors and a new president took control of Invacare in 1979. They first identified the need for the Power Rolls® IV in January 1980, following extensive market research. This research sought to answer the questions:

- What is currently available in wheelchairs?
- What do users want?
- What end product will satisfy these desires?

Invacare's study took about 4 months to complete. During that time Invacare talked with therapists in rehabilitation centers and hospitals and with dealers and users.

The marketing and engineering departments worked together to translate the comments and suggestions they received into technical concepts for an end product. For example, a user's comment that, "I don't want my chair to run away from me. Why does it gain so much speed going downhill?" was translated into the concept of dynamic braking. The technology developed had to be simple enough for dealers to service, and safe enough to convince therapists of its benefits for users.

While conducting its market survey, Invacare hired a market research firm to study wheelchair design. Talking to many of the same types of people, this research firm investigated what people would like a wheelchair to look like and presented a series of intermediate drawings and a final composite to Invacare. This design had to be modified to fit the limitations of the mechanics. For instance, the spacing of the wheels had to allow room for the batteries.

It took approximately 9 months from the time the idea was introduced to the time the first prototype was made. Several different prototypes were tested over the following 6 months for mechanical and electronic problems. Testing included subjecting the prototypes to extremes in temperature, testing battery life and battery heating during use, and using the prototypes in the field to make sure they performed appropriately.

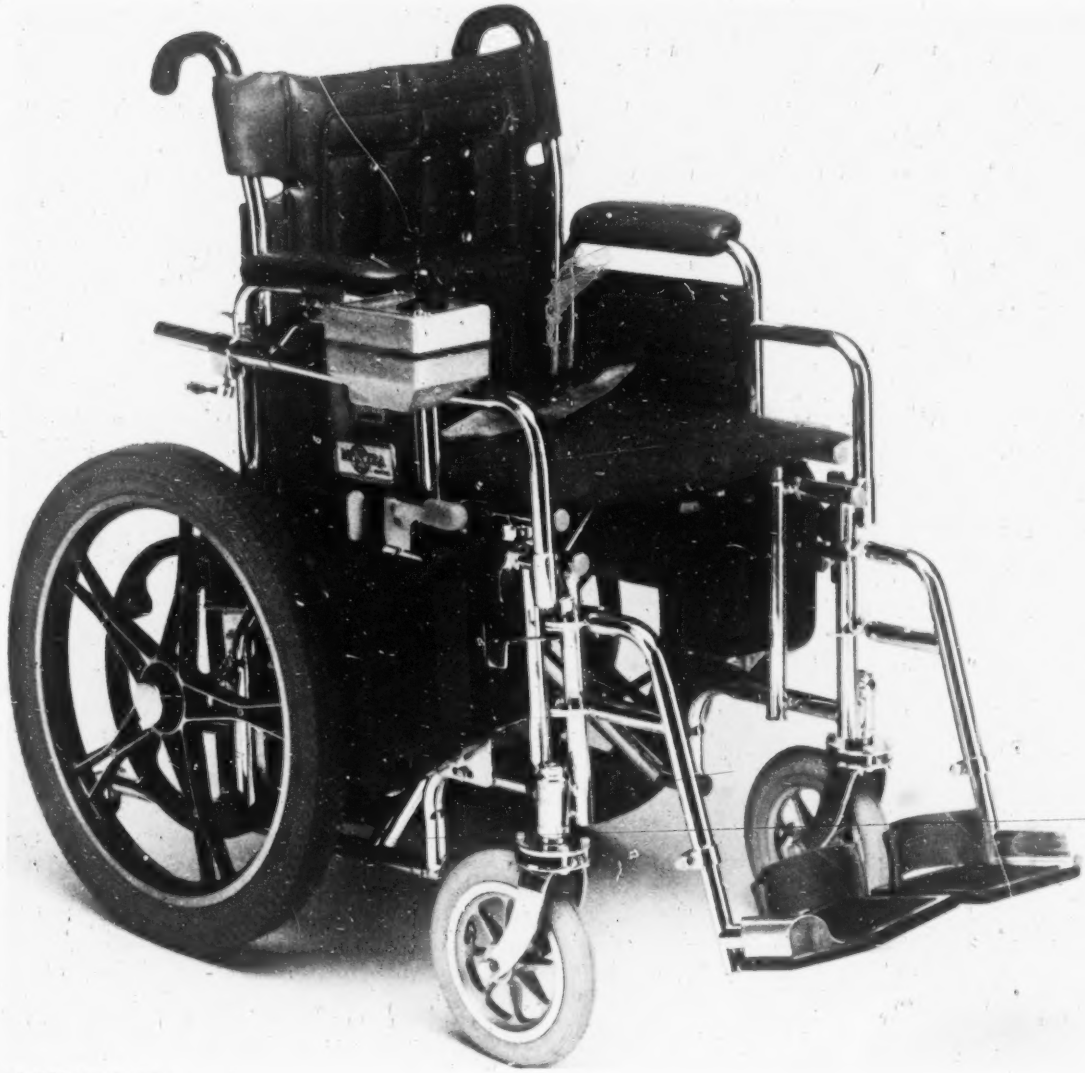
Commercial Introduction

The product was first introduced into commercial use through demonstrations in July 1981, with the first dealer delivery being made in September. The marketing strategy was developed along with the wheelchair. It was based on answers to the questions:

- What does the competition have?

[1]Information for these case studies, was obtained at the Invacare Corp. in Elyria, OH, on Aug. 17, 1983. The authors visited two manufacturing plant sites, headquarters offices, and the testing unit, and interviewed a number of company officials including the president, vice presidents in charge of engineering and marketing, product test technicians, and others.

Figure 1.—The Power Rolls® IV "Maxtra" by Invacare



SOURCE: Invacare Corp.

- How do they sell it?
- What success and failure are they having?
- How can we improve upon our competitors' problems?
- How can we explain and sell technical innovations such as "dynamic braking?"

When the product was ready in final form, Invacare's sales force attended demonstrations and were trained in the product's functions and use. The sales force was then authorized to begin to tell dealers about the product. Although the Power Rolls® IV was not yet for sale, dealers were

made aware that a new, substantially different power chair would be available shortly. They were discouraged from making large orders for other chairs until they saw what the new one had to offer. When the chair was finally made available, a promotional price was offered.

Diffusion of the Innovation

By the end of 1983 (2½ years since its introduction), the chair had captured 25 to 30 percent of the power wheelchair market.

Invacare credits its success in marketing the Power Rolls® IV to its sales force. It was responsible for convincing dealers and therapists that the product is worth selling and prescribing. Invacare also conducted training sessions for therapists. If the therapist was part of a large rehabilitation center, demonstration models were made available for use. Dealers were educated in the maintenance of the product. The product was priced to dealers to allow them a reasonable markup within their reimbursement allowance.

The two largest impediments to the innovation were price and product liability. The price had to be within the range the market would bear, given the prices of existing power wheelchairs and reimbursement constraints. Product liability was a crucial factor in the development of the Power Rolls® IV because the electronics were a new design. Product liability has not been a great concern in the revisions since then, as the product has now been proven.

Diffusion of the innovation to other manufacturers has taken several years. Everest & Jennings is said to be working on a similar product. They have marketed a product whose performance falls between those wheelchairs previously available and the Power Rolls® IV.

Discussion

The introduction of the Power Rolls® IV represents a combination of "technological push" and "demand pull." "Technological push" is a theory of innovation that says innovations are a product of improved technology's making innovation possible. Without the technology of dynamic braking and self-correcting steering (a capability of the electronic controller), the innovation would not have been possible. However, had it not been for users wanting a product with those features, i.e., "demand pull," the chair would not have been made (23).

The speed of the diffusion of the Power Rolls® IV may have been enhanced by the demand pull, but diffusion to other manufacturers has been time-consuming. The two main reasons for the lag are: First, the competitor must watch the sales of the new product to determine if it is successful and worth imitating. Second, once that decision is made, the competitor must develop and market the product. This process can take as much time as the original development of the innovation.

Diffusion to users can also be aided by directly approaching the users through, for example, advertising in user journals, such as *Paraplegia News* or *Accent on Living*. Users may also be reached in rehabilitation centers. The same training sessions that are conducted for the therapists may be open to the users.

CASE 2: POTENTIAL INNOVATION: CURB-CLIMBING WHEELCHAIR

Description of Innovation

Users of wheelchairs face obstacles to daily living that most people never think of, such as sidewalk curbs and other uneven surfaces. An innovation that has yet to be introduced to this country, although it is available elsewhere, is a curb-climbing wheelchair. It can also climb hills and navigate on ice and snow. A German model has tractor tread, much like that used on a tank. A Swedish model, available for 15 years, has large wheels and a large motor.

Obstacles

Why, if the technology exists, has this type of wheelchair not been introduced in the United States? Although some U.S. manufacturers are,

in fact, working on just such a chair, there is still a considerable lag time. Four reasons for this delay were identified (23).

First and most significant is product liability. The German model can sit on a steep stairway, but many people would have a difficult time maintaining balance at such a steep angle. The addition of a seat belt and shoulder strap is no guarantee of safety: people can forget to use them, and seat belts can break. Regardless of whether an accident is caused by a neglectful user or product malfunction, the manufacturer is at risk.

The second reason is funding. The R&D efforts to produce a curb-climbing wheelchair as a safe product are very costly and would need to be reflected in the price to the purchaser, estimated at $10,000 (23). It is doubtful that many third-party payers would be willing to pay for such an item, or that many users would be able to afford it themselves. Even if third-party coverage was obtained, a copayment of 20 percent or more (depending on allowable charge limitations) under private insurance or Medicare would be a significant obstacle. The market is too small and reimbursement too limited to make this innovation a priority for any company. Apparently, this has not been a problem for European manufacturers, as the Government and private insurance reimbursements tend to be more complete.

The third reason relates to user preference. U.S. manufacturers believe that American consumers like streamlined devices; the curb-climbing chair, as it is currently designed, is very heavy and bulky. Manufacturers believe that even if users have the desire and money to purchase such a wheelchair, they will be displeased with the design.

The final reason has to do with the technology transfer between countries. Although U.S. manufacturers could design their own models of a curb-climbing wheelchair, it is less costly to obtain the technology from companies already making the product. These companies are, in principle, willing to license their knowledge to U.S. manufacturers; but the U.S. manufacturer finds the licensing negotiations difficult, feeling that the foreign companies have an exaggerated conception of the size and wealth of the U.S. market. The U.S. companies have so far been unable to meet the demands of the foreign companies and are not likely to invest the money needed to develop the product on their own.

Foreign manufacturers have not yet exported these chairs directly to the United States and are unlikely to do so for almost the same reasons that innovations are not being made in this country. The cost of manufacturing is high and is increased even further by import taxes. Under U.S. reimbursement systems, the importing manufacturers would face the same reimbursement difficulties as domestic manufacturers. Last, European manufacturers, who have sufficiently valuable assets and reputations, are subject to the same product liability risks as U.S. manufacturers.

Appendixes

Appendix A.—Acknowledgments and Health Program Advisory Committee

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Jay AuWerter
Invacare Corp.
Elyria, OH

Peter W. Axelson
Veterans Administration
Palo Alto, CA

Henry Bergman
Public Citizen Health Research Group
Washington DC

Robert J. Britain
Food and Drug Administration
Department of Health and
Human Services
Washington, DC

Guy E. Clark
Barrier-Free Design Consultants, Inc.
Sub Lakes, AZ

Larry Comella
Food and Drug Administration
Department of Health and
Human Services
Silver Spring, MD

Clyde C. Cook
Veterans Administration
Washington, DC

J. Richard Crout
Boehringer-Mannheim Corp.
Rockville, MD

Donald L. Custis
Veterans Administration
Washington, DC

Patricia Dumphy
Massachusetts Department of
Public Welfare
Boston, MA

Gil Haury
Invacare Corp.
Elyria, OH

Douglas Hobson
Rehabilitation Engineering Program
University of Tennessee
Memphis, TN

Ralf Hotchkiss
Oakland, CA

David L. Jaffe
Veterans Administration
Palo Alto, CA

Malle Kasprzyk
Blue Cross and Blue Shield of
Massachusetts
Boston, MA

Carolyn Keeley
Massachusetts Department of
Public Welfare
Boston, MA

Ron Lipskin
Veterans Administration
New York, NY

Jan Little
Medical Equipment Distributors, Inc.
Maywood, IL

Donald Marlowe
Center for Medical Devices
Rockville, MD

Lee Matthews
Food and Drug Administration
Department of Health and
Human Services
Silver Spring, MD

Samuel R. McFarland
Southwest Research Institute
San Antonio, TX

Colin A. McLaurin
Rehabilitation Engineering Center
University of Virginia
Charlottesville, VA

Donald Milani
Abbey Medical
Brighton, MA

A. Malachi Mixon III
Invacare Corp.
Elyria, OH

Harold Pellerite
Food and Drug Administration
Department of Health and
Human Services
Silver Spring, MD

Jacquelin Perry
Rancho Los Amigos Hospital
Downey, CA

Hymie Pogir
Invacare Corp.
Elyria, OH

Anton Reichenberger
Veterans Administration
New York, NY

Nigel Shapcott
Rehabilitation Engineering Center
University of Tennessee
Memphis, TN

David Wayne Smith
University of Arizona
Tucson, AZ

Robert E. Smith
Veterans Administration
Palo Alto, CA

Anne R. Somers
Department of Environment and
Community and Family Medicine
Rutgers University
New Brunswick, NJ

Anthony Staros
Ortho-Tech International, Inc.
New York, NY

Gordon Stout
Berkeley, CA

Robert A. Streimer
Health Care Financing Administration
Department of Health and
Human Services
Baltimore, MD

Joseph Traub
National Institute of
Handicapped Research
Department of Education
Washington, DC

Raymond P. Whitten
National Aeronautics and
Space Administration
Washington, DC

Irving Kenneth Zola
Brandeis University
Waltham, MA

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Pan American Health Organization
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San Francisco, CA

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Norton Nelson
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New York, NY

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Associate Dean
University of Texas, San Antonio
San Antonio, TX

Nora Piore
Senior Advisor
The Commonwealth Fund
New York, NY

Mitchell Rabkin*
President
Beth Israel Hospital
Boston, MA

*Until April 1983.
**Until March 1984.
***Until October 1983.
****Until August 1983.

Dorothy P. Rice
Regents Lecturer
Department of Social and Behavioral Sciences
School of Nursing
University of California, San Francisco
San Francisco, CA

Richard K. Riegelman
Associate Professor
George Washington University
School of Medicine
Washington, DC

Walter L. Robb
Vice President and General Manager
Medical Systems Operations
General Electric Co.
Milwaukee, WI

Frederick C. Robbins
President
Institute of Medicine
Washington, DC

Rosemary Stevens
Professor
Department of History and Sociology of Science
University of Pennsylvania
Philadelphia, PA

Appendix B.—Sampling Procedures for Survey of Manufacturers

For feasibility, the survey was initially limited to 10 of the 53 eligible manufacturers listed in the National Rehabilitation Information Center's data bank, ABLEDATA. The technique of sequential proportional selection (sampling with probability proportional to size) was used to choose the companies. To obtain a reasonable representation of the industry, larger companies were given a greater chance of being chosen than smaller companies. This was accomplished not by using sales data, for they were unavailable, but through ABLEDATA information on the number of products listed for a company.

All the manufacturers identified through ABLEDATA's listings of manual, power, sports, and power alternative wheelchairs were ranked according to the number of listed products they made, n, from least (1) to greatest (32). Within a given size, companies were listed alphabetically. Foreign companies without U.S. distributors were not included. The cumulative numbers, N, were calculated (table B-1). The grand total, G (the final N) was divided by 10, the desired sample size, to give the sampling interval.

Any company that manufactured a greater number of products than the interval was automatically included in the sample. Companies and their products thus included were subtracted from the sample frame, giving a reduced total of products, T. A new interval was computed based on the number of companies remaining to be selected and T.

A random starting point was chosen using a random number table. The sampling interval was added to that starting point once for each company wanted for the sample. The companies whose cumulative N equaled or first exceeded each total, beginning from the top of the list, were chosen for the survey. When one company declined to participate due to time constraints, a replacement was chosen by continuing the process of sequential selection. This procedure provided the first 10 participants.

Table B-1.—Sampling Frame for Survey of Wheelchair Manufacturers

n[a]	Company	N[b]	n[a]	Company	N[b]
1	Abbey	1	1	Solo	25
1	Alpha	2	1	Steven	26
1	Bair	3	1	21st Century	27
1	Braun	4	1	X L	28
1	E. F. Brewer	5	2	Accumec	30
1	ChairLift	6	2	Amigo	32
1	Convaid	7	2	Damaco	34
1	Equalizer	8	2	E&J Canadian	36
1	Falkenberg	9	2	Hall's	38
1	General Engines	10	2	Production Research	40
1	Ja-Dik	11	2	Quadra	42
1	Kimed	12	2	Summit	44
1	Mastercraft	13	2	Wheeler Dealer	46
1	Mobility Engineering	14	4	Carter	50
1	Mobilizer	15	4	Voyager	54
1	Motion Designs	16	5	Newton	59
1	Motovator	17	6	International Medical Equipment	65
1	L. Mulholland	18	8	Invacare	73
1	National Welded	19	8	Ortopedia	81
1	Ortho-Kinetics	20	9	A-Bec	90
1	Ortop	21	14	Colson	104
1	Rosenthal	22	14	Sears	118
1	Seidel	23	15	Stainless	133
1	Sherry	24	32	E&J	165

[a] "n" is the number of products made by each company.

[b] "N" is the running total of the number of products made, n. Computations: G, the grand total, equals 165. The number of companies desired for sample equaled 10. The initial interval was 165 ÷ 10 = 16.5, so E&J was automatically included in the sample. The revised interval was calculated by noting that T, the revised grand total after E&J selection, is 165 − 32 = 133, and 133 ÷ 9 = 14.8. We rounded the result down (to 14). (If the interval was rounded up to 15, the final total, G, would be greater than 133, so we would not be able to select the last manufacturer.) The random starting point equaled 13 (from a random number table with range of 1 to 14). We added 14 to 13 repeatedly to get 9 totals: 13, 27, 41, 55, 69, 83, 97, 111, 125. The companies chosen were those whose N was equal to one of the totals or were the first to exceed one of the totals.

An additional manufacturer was chosen by a continuation of this process, adding 14 to the last total, 125. Since 139 is greater than 133 (T), we recycled to the beginning of the sample frame. The newest total became 139 − 133 = 6, so the sixth manufacturer was chosen as the replacement.

SOURCE: Derived from U.S. Department of Education, National Institute of Handicapped Research, National Rehabilitation Information Center. ABLEDATA System, 1983.

Appendix C.—Interviewer's Schedule for Telephone Interview of Wheelchair Manufacturers

Part I: General Information

1. a. What do you believe to have been your company's most significant innovations in the last 10 years?
   b. Briefly describe those innovations.
   c. What advantages do these innovations have over previous products?
   d. Are these innovations:
      - currently on the market?
      - no longer on the market?
      - expected to be on the market in the future?
2. Which of the above innovations were most important for the sales of your company? (Please limit to 3.)

Part II: Specific Past Innovations

3. a. When was the need for this innovation first identified? (month, year)
   b. When was the first prototype of this innovation constructed? (month, year)
   c. When was the innovation first offered for sale commercially? (month, year)
   d. When was the innovation first delivered commercially? (month, year)
4. Where did the idea for that innovation come from? For example, was it inspired by personal experience with wheelchairs, by an identifiable weakness in existing wheelchairs, by R&D efforts in another sector, or by something else?
5. Were the R&D efforts responsible for this innovation sponsored:
   - totally by the government?
   - mostly by the government?
   - half by the government, half by private concerns?
   - mostly by private concerns?
   - totally by private concerns?
6. Was this innovation approved for payment, in the State in which your company is headquartered, by:

	Yes, No, Don't Know	Date approved (month, year)	Length of approval process
Medicare			
VA			
Medicaid			
Other			
State of			

Part III: R&D and the Marketing Process

7. a. Does your company have an active R&D department of its own, or does it contract with R&D firms, or both?
   b. How important is R&D to your company as a whole? If possible, please express the amount spent on R&D as a percentage of gross annual sales.
   c. With what kinds of R&D is your company involved? The specific projects are not important, only the general areas of research. As with all of these questions, your answers are voluntary and confidential.
   d. Are there any innovations under development which you would be willing to describe?
8. a. What is your company's usual procedure for marketing a new or substantially improved product?
   b. What factors tend to be the largest impediments to the rapid marketing of new or substantially improved products?
9. a. When designing a new or substantially improved product, do you take into account voluntary standards in existence or expected to be in existence in the future?
   b. If you do consider any voluntary standards, which have the most influence on product design:
      - Veterans Administration?
      - Rehabilitation Engineering Society of North America (RESNA)?
      - International Standards Organization (ISO)?
   c. If advance copies of proposed RESNA standards were made available to you, would they influence product design and innovation?
10. a. Are there any government or Federal agency policies which affect R&D?
    b. Which ones?
    c. What effect do they have?
11. a. Do you actively participate in getting your product approved for third-party payment by government and private insurers?
    b. Describe this participation process.
    c. Does this process have an effect on the decision to design a new product or on the design of a new or substantially improved product?
12. a. Do you have any objections to our identifying one of your innovations, described in Section II, in our report?
    b. Would you like to have your company identified in our report? Do you object to it being identified in our report?

Appendix D.—Glossary of Terms and Acronyms

Glossary of Terms

ABLEDATA System: Computer data bank of the National Rehabilitation Information Center.

Discounting: A procedure used in economic analysis to reduce to present value those costs and benefits that will occur in future years. Discounting is based on two premises: 1) individuals prefer to receive benefits today rather than in the future; and 2) resources invested today in alternative programs could earn a return over time.

Health maintenance organization: An organization that acts as both insurer and provider of comprehensive but specified medical services by a defined set of physicians to a voluntarily enrolled population paying a prospective per capita amount.

Innovation: Any product or product modification that substantially improves the quality or decreases the cost of a product, while introducing a technology, material, or concept not previously found in any similar product on the market.

Manual wheelchairs: Type of wheelchair built in the traditional chair shape with wheels instead of legs. It may be propelled by the user's hands or feet or pushed by another person.

Power alternatives: Motorized vehicles that function like power wheelchairs but do not look like typical wheelchairs; most have three wheels and resemble golf carts or motor scooters.

Power wheelchairs: Motorized wheelchairs, usually battery-powered, which are heavier than manual wheelchairs.

Process innovations: Changes in the means of production.

Product innovations: Changes in the final product.

Total annualized costs: Annual overall costs of (wheelchair) use, calculated by taking the sum of: 1) the purchase price divided by a factor based on expected years of use and, 2) the annual repair and maintenance costs.

Glossary of Acronyms

ABLEDATA	— Computer Center at National Rehabilitation Information Center
ANSI	— American National Standards Institute
CID	— Commercial Item Description
CPV	— cumulative present value
E&J	— Everest & Jennings, Inc.
FDA	— Food and Drug Administration, U.S. Department of Health and Human Services
FTE	— full-time equivalent
GSA	— General Services Administration
HCFA	— Health Care Financing Administration, U.S. Department of Health and Human Services
HMO	— health maintenance organization
HUD	— Housing and Urban Development
ISO	— International Standards Organization
NIHR	— National Institute for Handicapped Research, U.S. Department of Education
OTA	— Office of Technology Assessment, U.S. Congress
R&D	— research and development
UMTA	— Urban Mass Transportation Administration
VA	— Veterans Administration

References

References

1. AuWerter, J., Chief Financial Officer, Invacare Corp., Elyria, OH, personal communications, June 12 and Aug. 20, 1984.
2. Awad, R. E., "Rehabilitation Technologies and Innovation: A Case Study of Medi-Cal Reimbursement Procedures and Their Impact on Diffusion," unpublished Master's thesis, Stanford University, 1983.
3. Carr, B., "Invacare Market Model," unpublished, Invacare Corp., Elyria, OH, 1983.
4. Cassak, D., "Forecast '80: $9.5 Billion Bonanza," *Surgical Business* 43(1):26, January 1980.
5. Comella, L., Division of Product Surveillance, Office of Compliance, National Center for Devices and Radiological Health, Food and Drug Administration, U.S. Department of Health and Human Services, Silver Spring, MD, personal communication, Sept. 1, 1983.
6. *Congressional Record*, Nov. 4, 1977.
7. Dumphey, P., Medical Division, Massachusetts Department of Public Welfare, Boston, MA, personal communication, June 16, 1983.
8. Haury, G., Vice President, Wheelchair Engineering, Invacare Corp., Elyria, OH, personal communication, Aug. 17, 1983.
9. Invacare Corp., market study, Elyria, OH, 1983.
10. Kamien, M. I., and Schwartz, N. L., *Market Structure and Innovation* (New York: Cambridge University Press, 1982).
11. Kasprzyk, M., Blue Cross and Blue Shield of Massachusetts, Boston, MA, personal communication, June 15, 1983.
12. Keeley, C., Medical Division, Massachusetts Department of Public Welfare, Boston, MA, personal communications, June 16 and 27, 1983.
13. Lipskin, R., Veterans Administration Rehabilitation Engineering Center, New York, personal communication, Aug. 25, 1983.
14. Marlowe, D., engineer, National Center for Devices and Radiological Health, Food and Drug Administration, U.S. Department of Health and Human Services, Washington, DC, personal communication, June 15, 1983.
15. Matthews, L., Regulatory Guidance Branch, Food and Drug Administration, U.S. Department of Health and Human Services, Silver Spring, MD, personal communication, Aug. 12, 1983.
16. McVey, A. V., "Wheelchair Survey Report," *Paraplegia News*, September 1982, pp. 42-46.
17. Medsger, B., "The Most Captive Consumers: At the Mercy of the Wheelchair Barons," *The Progressive*, March 1979, pp. 34-39.
18. Milani, D., Abbey Medical, Boston, MA, personal communication, Aug. 22, 1983.
19. Mixon, A. M., III, President, Invacare Corp., Elyria, OH, personal communication, Aug. 16, 1983.
20. Moss Rehabilitation Hospital, *Wheelchair I: Report of a Workshop*, contract No. 101(134)P-563 submitted to the U.S. Veterans Administration, and grant No. 23P-55518/3-06 submitted to the Rehabilitation Services Administration, U.S. Department of Health, Education, and Welfare, Washington, DC, 1978.
21. Nelson, R., Yale University, New Haven, CT, personal communication, Aug. 15, 1984.
22. Pellerite, H., Product Monitoring Branch, Division of Product Surveillance, Office of Compliance, National Center for Devices and Radiological Health, Food and Drug Administration, U.S. Department of Health and Human Services, Silver Spring, MD, personal communication, June 28, 1984.
23. Pogir, H., Director, Wheelchair Marketing, Invacare Corp., Elyria, OH, personal communication, Aug. 17, 1983.
24. Poister, T. H., "Federal Transportation Policy for the Elderly and Handicapped: Responsive to Real Needs?" *Pub. Admin. Rev.* 42(1):6-14, January-February 1982.
25. *Predicasts Forecasts*, No. 91, Apr. 22, 1983.
26. Rehabilitation Engineering Society of North America and U.S. Veterans Administration, *Wheelchair III: Report of a Workshop on Specially Adapted Wheelchairs and Sports Wheelchairs*, Bethesda, MD, 1982.
27. Reichenberger, A., U.S. Veterans Administration Prosthetics Center, New York, personal communication, July 2, 1984.
28. Traub, J., National Institute of Handicapped Research, U.S. Department of Education, Washington, DC, personal communication, Dec. 20, 1983.
29. U.S., *Federal Register*, 42(239):62,589-62,591, Dec. 13, 1977.
30. U.S., *Federal Register*, 46(239), Dec. 7, 1981.
31. U.S., *Federal Register*, 48(227):53,032, Nov. 23, 1983.
32. U.S. Bureau of the Census, *Statistical Abstract of the United States: 1981*, 102d ed., Washington, DC, 1981.
33. U.S. Bureau of the Census, *Statistical Abstract of the United States: 1982-83*, 103d ed., Washington, DC, 1982.
34. U.S. Bureau of the Census, unpublished data, 1983.
35. U.S. Congress, Office of Technology Assessment, *Federal Policies and the Medical Devices Industry*, GPO stock #052-003-00965-0 (Washington, DC:

U.S. Government Printing Office, September 1984).
36. U.S. Congress, Office of Technology Assessment, *Technology and Handicapped People*, GPO stock #052-003-00874-2 (Washington, DC: U.S. Government Printing Office, 1982).
37. U.S. Department of Education, National Institute of Handicapped Research, National Rehabilitation Information Center, ABLEDATA System, 1983.
38. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, *NIH Data Book, 1983*, Bethesda, MD, 1983.
39. U.S. Office of Management and Budget, "'Discount Rates To Be Used in Evaluating Time-Distributed Costs and Benefits," circular No. A-94, Washington, DC, Mar. 27, 1972.
40. U.S. Veterans Administration, *National AMIS Report for Fiscal Year 1982 (RCS10-64)*, Washington, DC, 1982.
41. U.S. Veterans Administration, *AMIS Report for VA Outpatient Clinic for Fiscal Year 1982*, Boston VA Outpatient Clinic, Boston, MA, 1982.
42. Whitten, R., chief, Terrestrial Applications Office, National Aeronautics and Space Administration, Washington, DC, personal communication, July 7, 1983.

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